

**The impact of a lack of medical explanation for pain,
'medically unexplained' comorbid conditions, and ethnicity
on CBT therapists' judgments of pain
and treatment decisions**

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

This three-part thesis reviews the effectiveness of cognitive behavioural therapies for medically unexplained symptoms on healthcare use, investigates the impact of a lack of a medical explanation for pain, 'medically unexplained' comorbid conditions, and ethnicity on CBT therapists' judgments of pain and treatment decisions, and discusses the challenges that were faced in the conducting and reporting of this research.

Part one of this volume is a review and meta-analysis of 16 randomised controlled trials of cognitive behavioural interventions for people with medically unexplained symptoms. Borderline significant effects were found for one analysis each of reduced healthcare contacts/resource use, as well as for medication use. There was no significant effect found for reduced medical investigations.

Part two of this volume is an empirical study that investigates the impact of a lack of a medical explanation for pain, 'medically unexplained' comorbid conditions, and ethnicity on CBT therapists' judgments of pain and treatment decisions. Small, but significant effects were found for the impact of a lack of a medical explanation for pain and comorbid conditions on CBT therapists' estimations of pain severity and exaggeration. A large effect was found for the impact of comorbid conditions on estimations of pain being caused by a mental health problem. These factors were also found to have an impact on treatment decisions. No effect on pain judgments was found for the variable of ethnicity, but ethnicity was found to have an impact on treatment decisions.

Part three is a critical appraisal of the literature review and research process as a whole. It contains some personal reflections on the different stages of research and the challenges that were faced.

Table of Contents

Overview	3
Acknowledgements	8
Part 1: Literature Review	9
Abstract	10
1. Introduction	11
2. Method	18
2.1 Search strategy	18
2.2 Inclusion and exclusion criteria	19
2.2.1 Types of studies	19
2.2.2 Participants	19
2.2.3 Interventions	19
2.2.4 Outcomes	20
2.3 Data collection and management	20
2.3.1 Study selection	20
2.3.2 Data extraction and management	21
2.4 Risk of bias	21
2.5 Meta-analysis of treatment effect	23
3. Results	24
3.1 Search	24
3.2 Participants	28
3.3 Diagnoses	28
3.4 Risk of bias analysis	30
3.4.1 Selection bias	30
3.4.2 Attrition bias	31
3.4.3 Detection bias	31
3.4.4 Reporting bias	32
3.4.5 Size bias	32
3.4.6 Treatment quality bias	32
3.5 Interventions	33
3.6 Healthcare use	35
3.6.1 Healthcare contacts and resource use	35
3.6.2 Medication use	37
3.6.3 Medical investigations	38
4. Discussion	39
4.1 Results of meta-analysis	39
4.2 Status of research on medically unexplained symptoms	41
4.3 Clinical and research implications	42
References	44
Part 2: Empirical Paper	56
Abstract	57
1. Introduction	58
1.1 History	58
1.2 Implications for clinical practice	61
1.3 Factors that influence pain judgments	64
1.3.1 Medical evidence	64
1.3.2 Patient factors	65
1.4 Impact on patients	68
1.6 Implications for psychological therapies	68

1.7 Rationale for current study	72
2. Research questions and hypotheses	73
2.1 Research Question 1 (hypotheses 1a – 1c)	73
2.2 Research Question 2 (hypotheses 2a – 2d)	73
2.3 Research Question 3 (hypotheses 3a – 3d)	74
2.4 Research Question 4 (hypotheses 4a – 4d)	74
2.5 Research Question 5 (hypotheses 5a – 5c)	74
2.5 Research Question 6 (hypothesis 6a)	75
3. Method	75
3.1 Setting and participants	75
3.2 Ethics	75
3.3 Design	76
3.3.1 Survey software and randomization	76
3.3.2 Online questions format	76
3.3.3 Vignette design and allocation	77
3.4 Power Analysis	79
3.5 Analysis	80
3.5.1 Pain judgments	80
3.5.2 ANOVA assumptions	80
3.5.3 Treatment decisions – impact of medical information and ethnicity	82
3.5.4 Treatment decisions – impact of participants' level of training	83
4. Results	84
4.1 Participants	84
4.1.1 Participant recruitment and attrition rates	84
4.1.2 Group allocation	84
4.1.3 Participant baseline characteristics and survey of training	85
4.2 The impact of medical information on pain judgments	86
4.3 Impact of comorbidity on pain judgments	89
4.4 Impact of ethnicity on pain judgments	90
4.5 Impact of interactions between variables on pain judgments	92
4.6 Impact of medical information and ethnicity on treatment decisions	92
4.7 Impact of training on treatment decisions	95
5. Discussion	97
5.1 The impact of a lack of medical explanation on CBT therapists' judgments of pain and treatment decisions	97
5.1.1 Pain minimisation	99
5.2 The impact of a comorbid medically unexplained condition on CBT therapists' judgments of pain and treatment decisions	99
5.3 The impact of ethnicity on CBT therapists' judgments of pain and treatment decisions, and the interaction between the variables of ethnicity and medical information	101
5.4 The impact of CBT therapists' levels of training on treatment decisions	104
5.5 Study limitations	105
5.6 Clinical and research implications	107
5.6.1 Clinical implications	107
5.6.2 Research implications	109
6. Conclusion	109
Acknowledgements	111
References	111

Part 3: Critical Appraisal	122
1. The start of the process	123
2. Negotiating a social minefield	125
3. Negotiating a semantic and theoretical minefield	127
4. Remembering the destination	128
5. Reflections on practical challenges	129
6. Conclusion	131
References	132

Appendices

Appendix 1: Example search strategy	133
Appendix 2: Ethical approval letter – UCL	134
Appendix 3: Confirmation of UCL sponsorship for recruitment in NHS Trusts	135
Appendix 4: Confirmation of NHS Trust Approval – BEH	136
Appendix 5: Confirmation of NHS Trust Approval – CNWL	137
Appendix 6: Confirmation of NHS Trust Approval – ELFT	138
Appendix 7: Confirmation of NHS Trust Approval – The Whittington Health NHS Trust	139
Appendix 8: Confirmation of NHS Trust Approval – NELFT	140
Appendix 9: Confirmation of NHS Trust Approval – WLMHT	141
Appendix 10: Recruitment email	142
Appendix 11: Online information sheet and consent form	143
Appendix 12: Computer-generated patient faces and pain expressions	147
Appendix 13: Written vignettes	149
Appendix 14: Internet-based questions	151

Tables and Figures – Table of Contents

Part 1: Literature Review	9
Figure 1: PRISMA Study Flow Diagram	26
Table 1: Included trials and follow-up studies: interventions, controls and modes of measuring healthcare use	27
Figure 2: Risk of bias graph: judgments of each risk of bias item presented as percentages across all included studies	30
Figure 3: Risk of bias summary: judgments of each risk of bias item for each included study	30
Figure 4: Forest plot of comparison 1 – healthcare contacts and resource use (continuous data)	36
Figure 5: Forest plot of comparison 2 – healthcare contacts and resource use (dichotomous data)	37
Figure 6: Forest plot of comparison 3 – medication use (continuous data)	38
Figure 7: Forest plot of comparison 4 – medication use (dichotomous data)	38
Figure 8: Forest plot of comparison 5 – medical investigations (continuous data)	39
 Part 2: Empirical Paper	 56
Table 1. Demographic information for participants	85
Table 2. Training information for participants	85
Table 3. Means (standard errors), <i>F</i> ratios, and <i>p</i> values, for the effect of medical information on pain judgments	87
Table 4. Pairwise comparisons (mean difference [standard error], <i>p</i> value, and 95% confidence intervals) of the effect of medical information on pain judgments.	88
Table 5. Means (standard errors), <i>F</i> ratios, and <i>p</i> values, for the effect of ethnicity on pain judgments	91
Table 6. Interactions between medical information and ethnicity on pain estimations	92
Table 7. Total cell frequencies and percentages (out of the overall responses in each category) of participants' treatment decisions by the variables of ethnicity and medical information	93
Table 8. Cell frequencies and percentages (of overall responses) of participants' treatment decisions by the variables of ethnicity and medical information, as well as interactions of these variables	94
Table 9. Partial associations, degrees of freedom, and <i>p</i> values for the interactions between the variables of ethnicity, medical information and treatment decisions	95
Table 10. Parameter estimates, <i>Z</i> scores and <i>p</i> values for the hierarchical model: interaction between ethnicity and treatment decisions, and interaction between medical information and decisions	95
Table 11. Cell frequencies and percentages of participants' treatment decisions by the variable of training	96
Figure 4. Percentages of participants in each training category who preferred CBT for depression, specialist referral, or specific treatment protocols for pain	97

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Part 1: Literature Review

**Effectiveness of cognitive behavioural therapies for medically
unexplained symptoms in reducing healthcare use:
systematic review & meta-analysis.**

Abstract

Background: Studies have reported that medically unexplained symptoms tend to be associated with increased healthcare use, and this can be a drain on resources and a potential source of harm to patients. This finding is often used as a justification for the funding and study of psychological interventions for medically unexplained symptoms, yet there has been no systematic review that has specifically examined the efficacy of psychological interventions in reducing healthcare use. **Aims:** To conduct a systematic review and meta-analysis to evaluate the effectiveness of cognitive behavioural therapies for medically unexplained symptoms in reducing healthcare use. **Method:** The search from a previous systematic review was updated and expanded. 19 randomised controlled trials were found that reported health care use, and 16 of these provided data for meta-analysis. **Results:** Borderline significant effects for cognitive behavioural therapies compared to active, treatment as usual and waiting list controls in reducing healthcare contacts and medication use. No benefits were found for reduction in medical investigations. **Conclusions:** These results indicate that cognitive behavioural interventions are not yet delivering on promises to reduce healthcare use in people with medically unexplained symptoms. The imprecise use of medically unexplained symptoms as a diagnostic label may impact on the effectiveness of interventions, and it is likely that the diversity and complexity of these difficulties may necessitate a more targeted approach.

1. Introduction

Despite increasingly rapid advances in biomedical science, symptoms and disorders that are described as medically unexplained remain common (Konnopka et al., 2012). A recent meta-analysis concluded that up to 49% of patients seen in primary care experience at least one medically unexplained symptom, and up to 34% would meet criteria for a somatoform disorder (Haller et al., 2015). This is not a new phenomenon; most health conditions were medically unexplained prior to the 20th century. However, as confidence has grown in the increasingly powerful and complex scientific methods developed to examine the physical body, so too has frustration and disbelief in symptoms that lie outside the sphere of our understanding.

Out of this struggle, new diagnoses and terminology have been used for describing what we do not fully understand: psychosomatic, somatoform, functional, and medically unexplained symptoms (MUS) or conditions are just some of these. Whilst the DSM and ICD focus on somatoform disorders, and policy-makers and service commissioners tend to focus on medically unexplained symptoms, the terms are broad and overlapping. All essentially describe the same thing: symptoms or symptom clusters that are deemed to be unexplained or inadequately explained by current science (Smith & Dwamena, 2007). These are diagnoses by exclusion that are in theory given once all medical tests have been exhausted and no physical cause can be identified (Brown, 2007; Price, 2008).

Giving these symptoms a categorisation or name, however, does not ameliorate the frustration they cause for the people who experience them or those tasked with providing treatment. Doctors have been shown to struggle with patients they cannot definitively diagnose and effectively treat (Chew-Graham et al., 2008; Mathers et al., 1995). Treating people who report symptoms for which no obvious structural abnormalities can be found, but who frequently attend appointments in states of distress and desperation, can leave health professionals feeling helpless

and inadequate. They tend to doubt the authenticity of patients' experiences rather than the adequacy of their 'objective' tests for pathology, and suspect that patients are being deceptive or wasting resources (Shattock et al., 2013).

Patients also generally expect that doctors and scientists can at the very least determine the cause of their symptoms, if not also offer some sort of treatment, cure or relief. Experiences such as chronic pain and fatigue are debilitating and have a significant impact on people's ability to live their lives normally. When these experiences cannot be explained or treated, however, they can generate anxiety, helplessness, and hopelessness (Nettleton, 1982; Rhodes et al., 1999). Patients with medically unexplained symptoms often say they feel disbelieved, or that they are being wrongfully accused of having a mental health problem rather than a 'real' physical health problem (Sim & Madden, 1982; Stone et al., 2002). As a result, they can feel angry and resentful towards the doctors they feel should believe them and do more to help.

However, there are advances in explaining the unexplained. Some symptom clusters are so frequently observed that, although they are still classified as medically unexplained, defining features have been identified and theories about their aetiology are being developed or are now well established by science. Research on Chronic Fatigue Syndrome (CFS), for example, has indicated that it may be associated with autoimmune, adrenal, and psychosocial factors that are suggestive of a complex, multi-system aetiology (Hyong et al., 2006). Likewise, the gate-control theory of chronic pain has shown that the experience of pain is not dependent on the presence of injury, but rather on complex interactions between the brain, spinal cord, and peripheral nervous system (Melzack & Wall, 1965; Moayed & Davis, 2013). Beyond this, scientists are grappling with how to explain the experience of sensations in a limb that no longer or never existed (Saadah & Melzack, 1994), an unexplained itch so severe that the sufferer can scratch through their skull and into their brain while they sleep (Gawande, 2008; Wood et al., 2009),

and symptom relief from a placebo, even when the person taking it is aware that it is a placebo (Knecht et al., 1996; Schäfer et al., 2015).

These developments generate new hope for patients and doctors who struggle every day with medically unexplained symptoms. However, this gap between theory and knowledge has occurred on countless occasions over the history of medicine, and researchers, doctors and health policy advisors would be wise to remain cautious. There are many instances when theories about disease were found to be wrong only after harm was done to patients. For example, prior to developments in the late 1800s, the prevailing theory about infectious disease was that it was spread through 'miasmas', or noxious odours (Tulodziecki, 2011). In the UK, this prompted public health campaigns to promote the use of indoor sewer systems that would remove odorous excrement from people's homes via the water supply, with now obvious negative consequences for water-borne diseases such as cholera. However, scientists and public health officials were so wedded to this theory that, even after significant evidence was presented to discredit it during the 1854 Broad Street cholera epidemic in London, they continued practices that undoubtedly contributed to an increase in deaths due to the disease (Paneth et al., 1998). Thus, in this case, actions based on an incorrect theory were worse than doing nothing.

Today, people who experience symptoms or conditions that are medically unexplained are potentially vulnerable to unintended harm by medical professionals and researchers for a number of reasons. Firstly, for some patients, it remains a possibility that they are experiencing a medically explained condition that is difficult to diagnose and for which a lack of appropriate treatment could put their health at risk (Smith et al., 2007). For example, inflammatory and autoimmune conditions such as Rheumatoid Arthritis can be difficult to detect and may be misdiagnosed as a medically unexplained condition such as Fibromyalgia, potentially resulting in higher levels of joint damage (Fitzcharles & Boulos, 2003). Therefore, it is essential

that doctors rule out medically explained conditions, and remain open to the potential need for further investigations and changes in diagnosis.

On the other hand, patients with medically unexplained symptoms could potentially be harmed by overly intensive, invasive or unnecessary investigations and treatments (Price, 2008). Not only are the benefits of many of these treatments and investigations questionable, but they can also raise patients' anxiety about their health, and frustration with a healthcare system that seems unable to offer an explanation for their experiences or relief from their symptoms (Lipsitt et al., 2014). Aside from physical harm, unnecessary treatments and investigations are also a drain on limited financial and healthcare resources, whether that cost is borne by the individual patient or society as a whole (Konnopka et al., 2012).

Finally, whilst conditions remain unexplained, many researchers, doctors and patients understandably choose to develop, deliver and engage in treatments that are based on as yet unproven theories about the aetiology of symptoms. This is often a pragmatic and sensible choice that results in the delivery of treatments based on sound theory and research-based evidence, to patients who otherwise have limited options or hope of symptom relief. Nevertheless, these treatments still lie in the gap between theory and knowledge that so often in medical history has had negative results. In the most basic sense, medically unexplained conditions are to the present day what cholera was for people in the 1800s.

For MUS, the picture is further complicated by the imprecision and broad use of the term and the multiplicity of radically different - often unsubstantiated - theories about causation. For example, although the gate-control theory of pain is now well established by science (Moayedi & Davis, 2013), many health professionals and guidance documents (not to mention the general public) continue to believe and promote the psychodynamic theory – for which there is no scientific evidence - that pain can be the manifestation of suppressed emotion or mental health difficulties

(Brown, 2007; Department of Health, 2014; Commissioning Support for London, 2010; Nemiah et al., 1976; Rief & Broadbent, 2007; Smith et al., 2007).

Further, when 'diagnosing' symptoms as medically unexplained, medical evidence based on the physical structures of the body that can be easily observed or measured is often given precedence over evidence of a patient's functioning. In other cases, it seems that some conditions may continue to be classified as medically unexplained, not because there is insufficient scientific evidence of a causal mechanism, but because the medical community struggles to treat the condition or the patients seem to benefit in some way from psychological treatments.

For these reasons, it is vital that methodologically valid and thorough research is conducted not only to investigate the aetiology of medically unexplained symptoms, but also to examine the effectiveness of the treatments that are delivered and the processes by which these interventions bring about change. There are many, often conflicting theories about medically unexplained symptoms (Brown, 2007; Rief et al., 2007). Some models emphasise the impact of illness beliefs and avoidance of physical activity (Deary, Chalder, & Sharpe, 2006; Rief et al., 1999), while others, despite the complete lack of evidence, continue to maintain that physical symptoms can be the manifestation of suppressed emotion (Nemiah et al., 1976). As such, studies based on these different theories are likely to have different outcome measures. Research based on the former model will likely utilise measures of cognitions and beliefs, whereas studies based on the latter theory will probably include measures of emotional avoidance and psychological difficulties. Neither are necessarily wrong choices, but they are inadequate if not paired with more robust measures of target symptoms and outcomes, and recording of adverse events (Brown, 2007; Williams, Eccleston & Morley, 2012). Otherwise, these studies could be likened to 1800s officials in London measuring their risk of infection with their noses.

In the case of medically unexplained symptoms and conditions, many of the studies of the efficacy of psychological interventions tend to measure treatment success in terms of the factors that the treatment was intended to change, such as illness beliefs, self-rated quality of life, and mood. However, they often do not assess physical functioning or wellbeing, or they do so in a way that does not reflect meaningful changes in functioning from the participants' perspective (Agardy, 2013). Measures specifically designed for medically unexplained symptoms, because of their theoretical underpinning, are often intrinsically linked to mood, which can impact on the responses participants give in terms of their physical functioning (Tomenson et al., 2013). And, far too frequently, research on medically unexplained symptoms relies exclusively on self-report measures. It is disappointing that more robust ways of measuring improvement are not developed and utilised and, as a result, a study participant could continue to live with significant levels of impairment, despite being presented as statistically improved in a research paper.

Due to the broad and often diffuse and overlapping diagnoses associated with the category of medically unexplained symptoms, as well as - often - the lack of physical markers or tests for measuring outcomes, it can be difficult to identify robust measures of treatment efficacy (Brown, 2007). Despite this, health policy makers and advisors have tended thus far to utilise increasingly broad and inclusive definitions for medically unexplained symptoms, and to commission services based on these categorisations (Department of Health, 2011, Department of Health, 2014; Commissioning Support for London, 2010). Whilst this decision is questionable and the framework it creates is likely not based on our best scientific understandings of 'medically unexplained' symptoms and conditions, it remains the norm. As such, it is the mandate that must be worked within for the time being. However, it complicates the picture for researchers and treatment providers who work within these

healthcare systems, as few outcome measures will be relevant to all medically unexplained symptoms.

One potentially more robust outcome that could be proposed is healthcare utilisation. People with medically unexplained symptoms are almost universally cited as high utilisers of healthcare resources, and this is considered to be a potential source of harm to patients, as well as a potential waste of resources (Konnopka et al., 2012; Price, 2008). Healthcare utilisation is an appropriately broad outcome that is likely to apply to most people with medically unexplained symptoms, and can be objectively measured through medical records. It also has specific applicability to the successful treatment of medically unexplained symptoms that, particularly in severe cases, are associated with unnecessary and potentially invasive or detrimental investigations and treatments.

In addition, a review of the literature on medically unexplained symptoms indicates that a great deal of service commissioning and studies of treatment effectiveness may in large part be justified by citing the costs associated with high healthcare utilisation. As a result, it would be prudent to measure whether the proposed interventions are indeed cost-effective. It is unclear how often this is done, although previous Cochrane reviews that focused on treatments for chronic pain or medically unexplained symptoms (or conditions deemed to be medically unexplained) either did not include healthcare use as an outcome (Bernardy et al., 2013; Zijdenbos et al., 2009) or did not meta-analyse the outcome due to a lack of data (Price et al., 2008). In a review by van Dessel et al. (2014), six of the studies reviewed provided data on post-treatment healthcare use, and no significant effect was found. Another Cochrane review on chronic pain (Williams et al., 2012) was followed up with an additional meta-analysis that found some moderate effects of psychological treatments on healthcare use in patients with chronic pain (Pike et al., 2016).

This review and meta-analysis will aim to investigate healthcare utilisation as an outcome in studies of interventions for medically unexplained symptoms. The literature search will draw from the studies included in a recent review of non-pharmacological interventions for somatoform disorders and medically unexplained symptoms (van Dessel et al., 2014). The search will also be updated and expanded to include all categories and diagnoses associated with medically unexplained symptoms (rather than just those that would only meet criteria for a somatoform disorder as in the van Dessel et al. [2014] review). As Cognitive Behavioural Therapy (CBT) is the most evidence-based intervention for both explained and unexplained conditions (Commissioning Support for London, 2010; Naylor, Parsonage, McDaid, Knapp, Fossey & Galea, 2012; Williams et al., 2012), the search will be limited to only that type of intervention. This review will also record the proportion of papers that cite healthcare use as a justification for their research, but do not measure it as an outcome.

2. Method

2.1 Search strategy

The van Dessel et al. review (2014) was first searched for trials reporting healthcare use as outcomes as well as at least one trial arm of a CBT-based intervention. The search from that review was then extended in three ways. Firstly, as this review is focused on trials of CBT-based treatments, search terms were added to specifically capture these studies. Secondly, although the previous review had focused on multiple MUS and excluded participants with “only one specific functional syndrome or symptom”, this review was intended to examine the category of MUS as a whole. The search was therefore extended to encompass all conditions currently classified as ‘somatic’, ‘functional’ or ‘medically unexplained’. Finally, the Cochrane Central Register of Control Trials (CENTRAL 2013), EMBASE, PsycINFO and MEDLINE were searched using the extended search strategy from January 2005 to December 2015. Appendix 1 includes an example search strategy (minor

adjustments were required for different databases). No additional restrictions were applied.

2.2 Inclusion and exclusion criteria

2.2.1 Types of studies

As in the van Dessel et al. review (2014), studies were included if they were full reports of randomised controlled trials (RCTs) or cluster randomised controlled trials (CRCTs), and were published in a peer-reviewed scientific journal.

2.2.2 Participants

Also in common with the previous review, participants were required to be 18 years or older and to have MUS as their primary problem. However, this review used the definition of MUS in the broadest sense, and therefore also included participants with not only diagnoses of multiple MUS or somatoform disorders, but also with single medically unexplained symptoms or disorders such as fibromyalgia (FMS), chronic fatigue syndrome (CFS), irritable bowel syndrome (IBS), temporomandibular disorders, and chronic pain (of at least 3 months duration in any body site). Participants with chronic pain or other symptoms (e.g. fatigue) associated with malignant disease or established medical diagnoses (e.g. rheumatoid arthritis) were excluded.

2.2.3 Interventions

Rather than including all non-pharmacological interventions, studies were included for this review only if the primary experimental intervention was based on CBT. This could include behavioural therapy (e.g. graded exercise, relaxation), third-wave CBT (e.g. mindfulness, acceptance and commitment therapy: ACT), and rehabilitation or 'stress reduction' programmes with a major component of CBT. In order to ensure that an appropriate level of fidelity to the model was achieved, it was required that these interventions be delivered or supervised by a qualified psychologist or healthcare professional with a recognised qualification in CBT. It

was also required that the primary mode of delivery of the intervention was face-to-face.

In addition to having a treatment arm based on CBT, eligible trials were required to have at least one comparator arm of another active intervention, attention or waiting list control, or treatment as usual.

2.2.4 Outcomes

Finally, included trials were required to measure healthcare utilisation as at least one outcome. All studies that reported measuring this outcome were included in the review. However, given the heterogeneous ways of measuring healthcare use (and in some cases, the failure to report full data), not all studies contributed usable data for analyses. Data were eligible for analysis regardless of how a patient accessed health services (e.g. self-referral, medical referral), the type of service used (e.g. outpatient visits, hospital admissions, procedures or tests), or how it was recorded (e.g. self-report, medical records). The data collected was in the form of health service visits, medication use, and number of treatments or medical investigations (diagnostic procedures or tests, e.g. laboratory tests, MRI, X-ray).

As participants engaged in an active treatment condition were regularly in contact with a healthcare service or professional, the use of other healthcare services during the course of a trial would be expected to decrease or remain stable over the course of treatment. As a result, eligible trials for analyses were required to present data on post-treatment healthcare utilisation.

2.3. Data collection and management

2.3.1 Study selection

First, duplicate records from the literature search were identified and discarded. The titles and abstracts of studies identified from the search were then screened, and those that obviously did not meet the inclusion criteria were excluded. The full texts of the remaining trials were examined, and studies were

identified for inclusion and exclusion. During this process, multiple reports on the same study were identified and collated.

The reasons for exclusion of studies were recorded. The number of reports that cited healthcare utilisation in the rationale for the study but did not use it as an outcome was also recorded.

2.3.2 Data extraction and management

Data were extracted on the final set of papers, including descriptive characteristics of participants, treatments and outcome measures. Further data from 3 authors (McCracken et al., 2013; Schmidt et al., 2011; Sleptsova et al., 2013) had been obtained for another review (Pike et al., 2016) and were shared for this analysis.

2.4. Risk of bias

A quality rating scale that generates numerical quality scores could have been used to assess the risk of bias for the trials in this review. However, these types of scales produce a composite score, wherein studies with very different qualities and risk of bias issues may attain an equal score. As a result, these scales can produce arbitrary results that do not reflect the most meaningful analysis of the quality of studies in a review. As a result, it was decided that each study would be individually assessed for bias using adapted Cochrane principles (Higgins & Green, 2011).

Of the suggested Cochrane risk of bias categories, performance bias as excluded because it is not possible to blind therapists and patients to the delivery or receipt of psychological therapy. The remaining suggested risk of bias categories of selection bias (randomised selection and allocation concealment), detection bias (outcome assessment blinding), reporting bias (selective reporting of results), and attrition bias (participant drop-out) were utilised as suggested in Cochrane guidance. In line with another meta-analysis on treatment of pain in a specific population (Baird et al., 2016) additional attention was paid to the way that studies managed

incomplete data (attrition bias). In addition, studies were examined for bias related to insufficient size and power, as well as the quality of the treatment delivered.

Attrition bias is particularly important to consider in research on psychological treatments for medically unexplained symptoms. Understandably, participants who have struggled with medically unexplained symptoms could interpret (and, sometimes, rightly so) psychological treatments as a confirmation that health professionals believe their symptoms are due to a mental health problem. As a result, many may not engage in treatment, either from the start or through dropping out partway through the intervention. Participants may also drop out of treatment if they are experiencing adverse effects or do not feel that they are benefiting. As a result, in order to reduce the risk of inflating or over-generalising treatment outcomes, it is imperative that studies on medically unexplained symptoms pay particular attention to the way in which they select participants and handle the data from those who do not complete treatment. In this review, studies were assessed as 'low risk' if less than 10% of participants did not complete the study or an intention to treat (ITT) analysis was completed with the conservative 'baseline measure carried forward', 'unclear risk' if more than 10% of participants did not complete the study and an algorithm to estimate missing values was used, or 'high risk' if more than 10% dropped out and only a 'completer' analysis was used.

Due to the broad use of the term medically unexplained symptoms and the difficulties this can generate in research on interventions, it is also important that studies utilise power calculations and ensure that their treatment groups are adequately sized in order to detect treatment effects. Studies were deemed to have a 'low risk' of bias due to insufficient size if they had reported a power analysis for their study and had met the size requirement, 'unclear risk' of bias if they reported a power analysis but did not meet the size requirement, and 'high risk' of bias if they did not report a power analysis and the size of the study was not clearly adequate.

As with all research on treatment effectiveness, but particularly in the case of non-pharmacological treatments, it is important to ensure that the specified intervention was actually delivered to participants and was of sufficient quality. In the case of medically unexplained symptoms, similar interventions could be based on very different theories about aetiology and maintaining factors and therefore have varied implementation, and it is important that this is critically examined when analysing treatment effects. In this review, studies that did not utilise suitably qualified healthcare professionals to deliver the specified treatment were excluded outright due to the risk of insufficient treatment quality. Trials that used a suitably qualified healthcare professional, but did not make any effort to check the quality and fidelity of treatment to the specified model, were assessed as having a 'high risk' of bias. Studies were deemed to have an 'unclear risk' of bias if they stated that treatment fidelity or quality was checked, but did not provide sufficient information on this. A rating of 'low risk' of bias was only given to trials that clearly stated how treatment quality and fidelity to the model were assessed, and adequately reported the results of this.

The 'Risk of bias' tool in the Cochrane Collaboration's RevMan5.3 software (The Cochrane Collaboration, 2014) was used to complete a risk of bias table for each study.

2.5. Meta-analysis of treatment effect

The RevMan5.3 software was also used to analyse data for the meta-analysis. Treatment effects for continuous data were estimated using standardized mean differences (through the extraction of means, standard deviations, and sample sizes). Treatment effects for dichotomous data were estimated using odds ratios (through the extraction of events data and sample sizes). Due to the diversity of data extracted, both continuous and dichotomous data were analysed using random effects. All calculations were made using 95% confidence intervals.

In the event that a study had two or more treatment groups that were CBT-based and met the inclusion criteria for this review, and/or two or more comparison groups, these were combined into a single treatment or comparison group. The heterogeneity of data (as indicated by the I^2 statistic) was calculated in RevMan and interpreted using Cochrane principles (The Cochrane Collaboration, 2011).

Studies that did not provide usable data for the meta-analysis were included in the narrative review.

3. Results

3.1. Search

The outcome and process of the literature search and study selection is summarised a PRISMA study flow diagram in Figure 1.

The initial search of the van Dessel et al. review (2014) resulted in six papers describing trials that measured healthcare use (Kolk et al., 2004; Lidbeck, 2003; Martin et al., 2007; Sattel et al., 2012; Schaefer et al., 2013; Sumathipala et al., 2008). However, only three had an exclusively CBT-based treatment arm, and two of these were excluded because the intervention was not delivered or supervised by a suitably qualified healthcare professional (rationale detailed in section 2.4) (Lidbeck, 2003; Sumathipala et al., 2008). Therefore, only one study from the previous review was included (Martin et al., 2007). The expanded and updated search resulted in 19 eligible trials (Allen et al., 2006; de Boer et al., 2014; Fjorback et al., 2013; Jensen et al., 2005; Kaapa et al., 2006; Luciano et al., 2013; Martin et al., 2007; McCracken et al., 2013; McCrone et al., 2008; McCrone et al., 2012; Meng et al., 2014; Nyenhuis et al., 2013; O'Dowd et al., 2006; Schmidt et al., 2011; Schröder et al., 2013; Siemonsma et al., 2013; Sleptsova et al., 2013; Thieme et al., 2006; van Ravesteijn et al., 2013). Table 1 provides details for these studies. In cases where a follow-up or economic analysis was completed that contributed the majority of data, this paper will refer to those studies rather than the original trial.

Trials identified from the expanded search were excluded for the following reasons. Two studies did not deliver a face-to-face intervention (Ljótsson et al., 2011; McBeth et al., 2012). One trial recruited participants who were still in the acute stage of pain (Stowell et al., 2007). Another study did not utilise an adequate control or randomisation procedure for the purposes of this review (Thorn et al., 2011). Finally, a further seven trials utilised interventions that were not delivered or supervised by a healthcare professional with a suitable qualification in psychology or a CBT-based treatment (Falcao et al., 2008; Froholdt et al., 2012; Goldstein et al., 2010; Jerant et al., 2009; Lindell et al., 2008; Luo et al., 2007; Miró et al., 2011).

Figure 1: PRISMA Study Flow Diagram

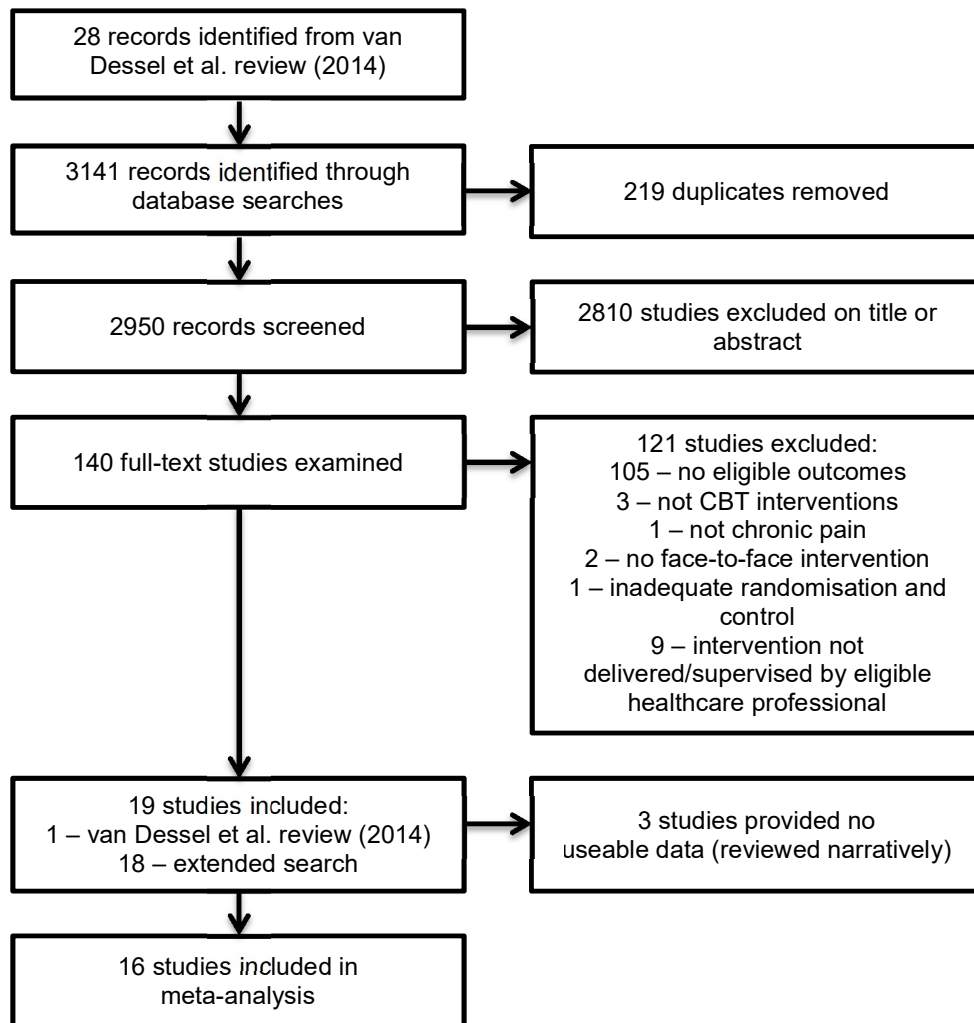


Table 1. Included trials and follow-up studies: interventions, controls, and modes of measuring healthcare use

Trials & Follow-ups	Intervention(s)	Control(s)	Mode of measuring healthcare use
Allen et al., 2006	CBT + Psychiatric Consultation Intervention (PCI)	PCI alone	Healthcare contacts Medical investigations
de Boer et al., 2014	CBT	TAU	Healthcare contacts
Fjorback et al., 2012 (cost-effectiveness study: 2013)	Mindfulness	TAU	Healthcare contacts
Jensen et al., 2001 (follow-up study: 2005)	CBT, Physical Therapy (PT) & Behavioural Medicine Rehabilitation	TAU	Healthcare contacts
Kaapa et al., 2006	Multidisciplinary Team (MDT) Rehab	PT	Healthcare contacts
Kennedy et al., 2005 (cost-effectiveness study: McCrone et al., 2008)	CBT + Medication	Medication only	Healthcare contacts
Luciano et al., 2011 (follow-up study: 2013)	CBT	TAU	Healthcare contacts/costs Medication costs Medical investigation costs
Martin et al., 2007	CBT	TAU	Healthcare contacts Medication use
Meng et al., 2015	CBT	TAU	Healthcare contacts, Medication use Medical investigations
McCracken et al., 2013	Acceptance and Commitment Therapy (ACT)	TAU	Healthcare contacts
Nyenhuis et al., 2013	CBT	Internet & Bibliotherapy interventions	Healthcare contacts
O'Dowd et al., 2006	CBT	TAU & Education Support Group	Healthcare contacts Medication use Combined costs
Schmidt et al., 2011	Mindfulness-based Stress Reduction (MBSR)	TAU & Attention control	Healthcare contacts Medication use
Schröder et al., 2013	CBT	Waitlist control	Healthcare contacts
Siemonsma et al., 2013	"Cognitive Treatment of Illness Perceptions" (CTIP)	TAU	Healthcare contacts Medication use
Sleptsova et al., 2013	CBT	Exercise	Healthcare contacts, medication use, & medical investigations
Thieme et al., 2006	CBT & Operant Behaviour Therapy (OBT)	Attention control	Healthcare contacts
van Ravesteijn et al., 2013 (cost-effectiveness study: 2013)	Mindfulness-based Cognitive Therapy (MBCT)	Enhanced usual care	Healthcare contacts & costs
White et al., 2011 (cost-effectiveness study: McCrone et al., 2012)	CBT, Adaptive Pacing Therapy & Graded Exercise Therapy	TAU	Healthcare contacts, medication costs

Note: TAU = Treatment as usual, CBT = Cognitive Behavioural Therapy

3.2 Participants

The 19 studies reviewed contributed a total of 3239 participants (mean 171) at the start of treatment, and 2668 (mean 140) at the end. Dropout was generally moderate across the studies, with a mean completion rate of 82%.

Two studies were conducted in the USA (Allen et al., 2006; Meng et al., 2014), and the rest in Europe. Participants had a wide age range from 18 to 75, with a combined average age of 45. As is commonly found in research on medically unexplained symptoms, the majority of participants were female (72%). Males outnumbered females in only two studies (N = 729, 54% males) (Nyenhuis et al., 2013; Siemonsma et al., 2013). Two studies had exclusively female participants (N = 293) (Schmidt et al., 2011; Thieme et al., 2006), and the remaining 15 studies recruited a majority of female patients (77%).

3.3 Diagnoses

Due to the broad and overlapping nature of conditions and symptoms described as medically unexplained, the 19 eligible trials recruited participants with a wide range of symptoms and complaints and used many different diagnostic labels.

No studies recruited patients based on the new DSM-5 diagnoses of Somatic Symptom Disorder or Illness Anxiety Disorder, which no longer have the requirement that symptoms be medically unexplained (American Psychiatric Association, 2013). Four studies (N = 441) recruited patients based on DSM-IV diagnostic criteria (American Psychiatric Association, 1994), the most common of which were Undifferentiated Somatoform Disorder (N = 173), Somatization Disorder (N = 133), and Pain Disorder (N = 56) (Allen et al., 2006; Martin et al., 2007; Schröder et al., 2013; van Ravesteijn et al., 2013). Of these four studies, two did not report the specific physical complaints of participants (Allen et al., 2006; Martin et al., 2007), one (Schröder et al., 2013) reported that the most frequent complaints were pain, dizziness, heart palpitations and fatigue, and the final study provided a

breakdown of complaints, including fatigue (N = 31), pain (N = 57), gastrointestinal symptoms (N = 13), and neurological symptoms (N = 11).

Nine studies included participants (N = 1172) with chronic pain or Fibromyalgia (a medically unexplained condition associated primarily with chronic pain) (de Boer et al., 2014; Jensen et al., 2005; Kaapa et al., 2006; Luciano et al., 2011; McCracken et al., 2013; Schmidt et al., 2011; Schröder et al., 2013; Sleptsova et al., 2013; Thieme et al., 2006). Four of these studies exclusively included participants with Fibromyalgia (N = 482) (Luciano et al., 2011; McCracken et al., 2013; Schmidt et al., 2011; Thieme et al., 2006). Amongst all nine studies, back and/or neck pain was a dominant complaint (N = 541).

Several studies focused on specific disorders currently classified as medically unexplained. One study recruited participants diagnosed with Irritable Bowel Syndrome (N = 149) (Kennedy et al., 2005), three studies recruited participants diagnosed with Chronic Fatigue Syndrome or presenting primarily with unexplained chronic fatigue (N = 904), and one study recruited participants with Tinnitus (N = 304).

Finally, one study (Fjorback et al., 2012) recruited patients with medically unexplained symptoms who met criteria for a newly proposed diagnosis of Bodily Distress Syndrome (N = 119). Participants in this study presented variably with chronic fatigue syndrome, fibromyalgia, non-cardiac chest pain, irritable bowel syndrome, hyperventilation syndrome, and tension headache.

3.4 Risk of bias analysis

Figures 2 and 3 provide overall summaries of the risk of bias for each study.

Figure 2: Risk of bias graph: judgments of each risk of bias item presented as percentages across all included studies

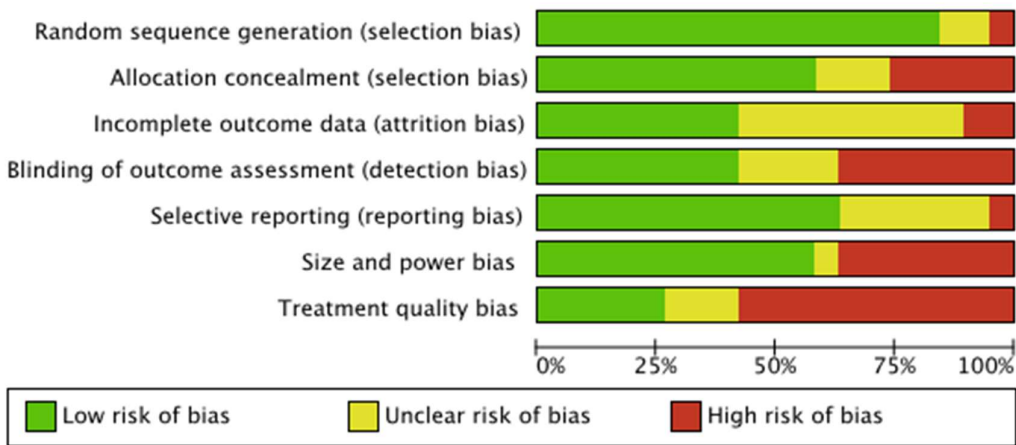
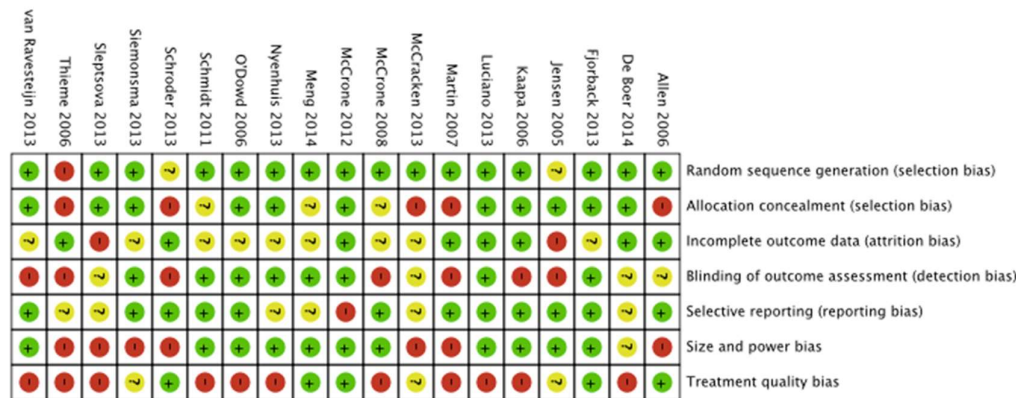


Figure 3: Risk of bias summary: judgments of each risk of bias item for each included study



3.4.1 Selection bias

Most studies were rated as low risk in terms of randomised selection of participants. Three studies either had potential problems with randomisation (Jensen et al., 2005) or did not give enough information on how randomisation was achieved (Schröder et al., 2013; Thieme et al., 2006). Five trials did not conceal group allocation or did not mention this in the report (Allen et al., 2006; Martin et al.,

2007; McCracken et al., 2013; Schröder et al., 2013; Thieme et al., 2006), and three further studies did not give enough information or presented potential problems with how concealment was attained (McCrone et al., 2008; Meng et al., 2014; Schmidt et al., 2011).

The majority of studies checked that participants in each group did not differ significantly on baseline characteristics, but only four studies measured participants' expectations for treatment in all groups (Allen et al., 2006; Kaapa et al., 2006; McCrone et al., 2012; Thieme et al., 2006).

3.4.2 Attrition bias

As expected from previous research and reviews, less than half of the studies (N = 8) either had less than 10% of participants drop out or used a conservative intention to treat analysis of 'baseline measure carried forward' (Allen et al., 2006; de Boer et al., 2014; Kaapa et al., 2006; Luciano et al., 2013; Martin et al., 2007; McCrone et al., 2012; Schröder et al., 2013; Thieme et al., 2006). The remaining studies (N = 11) had higher levels of attrition and conducted less conservative intention to treat analyses. One of these trials conducted only a 'completer' analysis and was assessed as a high risk of bias (Sleptsova et al., 2013). Another trial was assessed as high risk because, although the intention to treat results conflicted with the 'completer' analysis, they chose to use the 'completer' analysis in their interpretation of the study outcome (Jensen et al., 2005).

3.4.3 Detection bias

More than half of the trials (N = 11) either did not attempt to blind outcome assessors to participants' intervention condition (Jensen et al., 2005; Kaapa et al., 2006; Martin et al., 2007; McCrone et al., 2008; Schröder et al., 2013; Thieme et al., 2006; van Ravesteijn et al., 2013), had problematic concealment (de Boer et al., 2014), or did not provide enough information on how this was achieved (Allen et al., 2006; McCracken et al., 2013; Sleptsova et al., 2013).

3.4.4 Reporting bias

All studies provided reports on all outcomes, but five of these did not provide complete data associated with some results (McCracken et al., 2013; Meng et al., 2014; Nyenhuis et al., 2013; O'Dowd et al., 2006; Thieme et al., 2006). One trial was rated as 'unclear' risk of bias, as it utilised visual analogue scales and drawings to measure pain intensity and location, and these were not adequately described for interpretation of results (Sleptsova et al., 2013). The final trial was rated as 'high' risk of bias because it deviated from the protocol when reporting and analysing some outcomes, and this could have resulted in a positive interpretation of treatment effectiveness for participants who did not experience clinically meaningful improvement (McCrone et al., 2012). These deviations from protocol in the analysis and reporting of results in the McCrone et al. trial (2012) have been strongly criticised, and there have also been allegations regarding inadequate reporting of adverse events (Agardy, 2013).

3.4.5 Size bias

Five trials neglected to conduct a power analysis when planning recruitment (Allen et al., 2006; Martin et al., 2007; McCracken et al., 2013; Siemonsma et al., 2013; Thieme et al., 2006), and two studies conducted a power analysis (initially or post-hoc) and were underpowered (de Boer et al., 2014; Schröder et al., 2013). One trial was rated as a 'high' risk of bias because a power analysis was conducted using an estimated effect size based on "previous [clinical] experience" of delivering the intervention, and was likely underpowered (Sleptsova et al., 2013).

3.4.6 Treatment quality bias

Nearly half of the studies reviewed (N = 9) made no attempt to assess treatment quality or fidelity to the model (de Boer et al., 2014; Kaapa et al., 2006; Luciano et al., 2013; Martin et al., 2007; Nyenhuis et al., 2013; O'Dowd et al., 2006; Schmidt et al., 2011; Thieme et al., 2006; van Ravesteijn et al., 2013). Three studies made some efforts to ensure treatment quality, but these were either inadequate for

a 'low' risk of bias rating or were not fully reported (Jensen et al., 2005; McCracken et al., 2013; Siemonsma et al., 2013). One study was rated as 'high' risk of bias because, although it took some steps to ensure treatment quality (taped sessions for supervision), there were significant concerns regarding the dosage of treatment due to a high level of non-attendance in the treatment group (McCrone et al., 2008). Another study made only a very minimal effort to ensure treatment quality (supervision), but delivered a very high dose of treatment (25, 90 minute sessions), and provided limited information on the treatment protocol (Sleptsova et al., 2013).

3.5 Interventions

As specified in the inclusion criteria, all 19 studies included a CBT-based treatment (see section 2.2.3 for a definition of these). Most (N = 12) described a CBT treatment with elements aimed at addressing both cognitive and behavioural factors. Of the remaining studies, three utilised a mainly behavioural treatment (Luciano et al., 2011; Meng et al., 2014; Sleptsova et al., 2013), three focused on mindfulness or mindfulness-based cognitive therapy/stress reduction (Fjorback et al., 2012; Schmidt et al., 2011; van Ravesteijn et al., 2013), and one study delivered Acceptance and Commitment Therapy (ACT) (McCracken et al., 2013).

Most studies had two arms (N = 8), and half of these used a treatment as usual, or attention placebo control (Luciano et al., 2011; Martin et al., 2007; Siemonsma et al., 2013; Sleptsova et al., 2013). Although both 'waiting list' and 'treatment as usual' controls were specified by studies, participants on waiting lists were also presumed to be receiving treatment as usual. Of the four studies that used an attention placebo control, three of these were considered to be of good quality with equal numbers of sessions and a specified activity (exercise, relaxation/stretching, group support) and adequate rationale presented to the participants (Meng et al., 2014; Sleptsova et al., 2013; Thieme et al., 2006). However, the quality of the attention control in the remaining study was questionable

(information booklet, self management), and this was reflected in the high level of dropout in these groups (Nyenhuis et al., 2013).

One study combined CBT with a psychiatric consultation intervention (PCI), which instructed primary care physicians to see participants only during regularly scheduled appointments and limit additional diagnostic procedures and treatments, and compared this to PCI alone (Allen et al., 2006). Similarly, a study of treatment for IBS compared CBT and a drug treatment to drug treatment alone. Another study incorporated CBT into a multidisciplinary rehabilitation programme (an intensive package of treatment including occupational, physiotherapy, and exercise interventions) and compared this to individual physiotherapy (Kaapa et al., 2006). The remaining study compared face-to-face and Internet-delivered CBT (de Boer et al., 2014).

Four trials had three arms, and three of these compared one active treatment to attention, placebo, or treatment as usual controls (Meng et al., 2014; O'Dowd et al., 2006; Schmidt et al., 2011). For all analyses of these studies, the attention, placebo and treatment as usual controls were combined and compared to the active treatment. The remaining study compared two active treatments (CBT combined with behaviour therapy (BT) or BT alone) with an attention control (Thieme et al., 2006). For all analyses of this study, CBT with BT and BT alone were combined and compared with the attention control.

Finally, three studies had four arms. Two of these compared CBT with behaviourally oriented treatments and a 'specialist medical care' or treatment as usual control (Jensen et al., 2005; White et al., 2011). As all of the behaviourally oriented treatments met criteria for inclusion in this review, they were combined for all analyses and compared to the specified controls. The last study compared face-to-face CBT with Internet and bibliotherapy interventions as well as an 'information provision' control (Nyenhuis et al., 2013). This review did not provide usable data for analyses.

3.6 Healthcare use

Of the 140 full-text studies examined in the literature search, over half (N = 78) cited high healthcare utilisation as an indicator of the need for research on medically unexplained symptoms in the abstract or introduction of the report. 63% of these studies (N = 49) did not go on to measure healthcare use as an outcome.

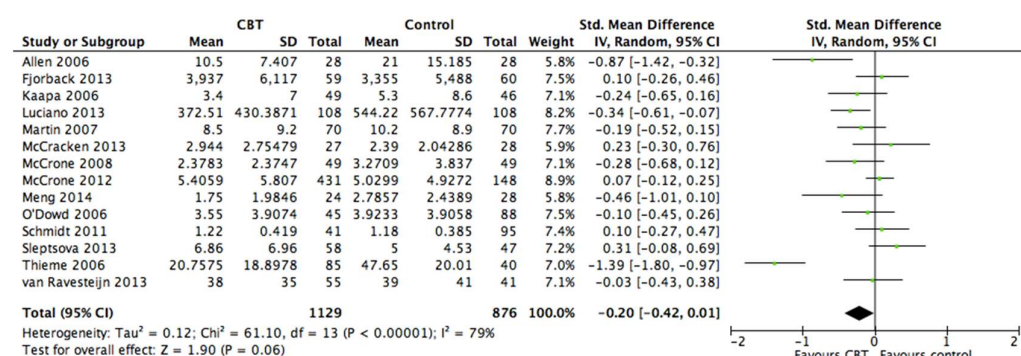
Of the 19 trials that were eligible for this review, 16 studies contributed usable data for meta-analysis of healthcare use outcomes. All trials assessed healthcare use at follow-up, and this varied in length from 8 weeks to 3 years. Some studies assessed healthcare use at more than one time post-treatment, and in these cases the latest measurement was chosen. Most trials (N = 13) collected data on healthcare use through self-report; one used insurance company records (Sleptsova et al., 2013), and four collected data directly from medical records (Allen et al., 2006; Fjorback et al., 2013; O'Dowd et al., 2006; Thieme et al., 2006).

3.6.1 Healthcare contacts and resource use

All sixteen studies with usable data contributed to the meta-analysis of healthcare contacts and resource use. Fourteen trials reported means and standard deviations (or data that were used to derive this information). Nine referred specifically to contacts with healthcare professionals (Allen et al., 2006; Kaapa et al., 2006; Martín et al., 2014; McCracken et al., 2013; Meng et al., 2014; Schmidt et al., 2011; Sleptsova et al., 2013; Thieme et al., 2006; van Ravesteijn et al., 2013), two to the cost of healthcare use (Fjorback et al., 2013; Luciano et al., 2013), and three provided data on both contacts and associated costs (McCrone et al., 2008; McCrone et al., 2012; O'Dowd et al., 2006). In the case of the latter three trials, data on healthcare contacts was used rather than costs, as that was the measure in common with the majority of trials in this review. The overall effect showed no significant difference between intervention and control in reduction of healthcare resource use: SMD = -0.20 (95% CI -0.42 to 0.01); $z = 1.90$, $p = 0.06$. Heterogeneity was high, at 79%.

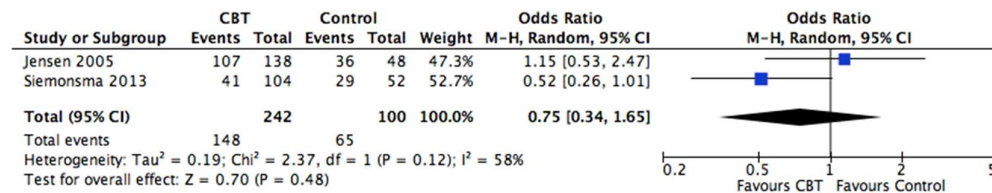
It was observed from the raw data that was obtained from three studies (McCracken et al., 2013; Schmidt et al., 2011; Sleptsova et al., 2013), that the data for healthcare use did not have a normal distribution. In addition, the way that data was presented in other trials (Allen et al., 2006; van Ravesteijn et al., 2013) also suggested that it was skewed. There was no evidence in the reports of these studies that any efforts were made to correct for this deviation from normality. This data was not excluded from the meta-analysis, because the method of analysis should be reasonably robust in handling deviations from normality. However, it calls into question the quality of data analysis in these trials, and their findings should be interpreted more cautiously.

Figure 4: Forest plot of comparison 1 - healthcare contacts and resource use (continuous data)



Two trials contributed event-related data to the healthcare contacts and resource use outcome, and these were analysed separately (Jensen et al., 2005; Siemonsma et al., 2013). The overall effect showed no significant difference between groups: OR = 0.75 (95% CI 0.34 to 1.65) z = 0.70, p = 0.48. Heterogeneity was moderate, at 58%.

Figure 5: Forest plot of comparison 2 - healthcare contacts and resource use (dichotomous data)

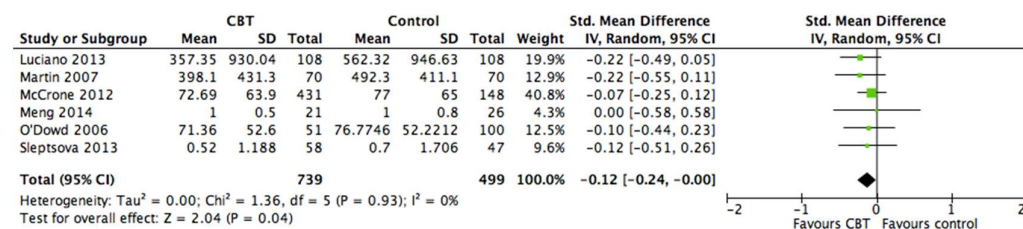


Three studies reported that they measured contacts with healthcare professionals, but did not provide usable data (de Boer et al., 2014; Nyenhuis et al., 2013; Schröder et al., 2012). Nyenhuis and colleagues (2013), and Schröder and colleagues (2012) reported no significant reduction in healthcare use between groups. De Boer and colleagues (2014) reported a marginal difference in costs favouring the control group (internet intervention). However, there was a large rate of drop-out in the control condition, and the authors reported that the difference was “negligible” following the intent to treat analysis.

3.6.2 Medication use

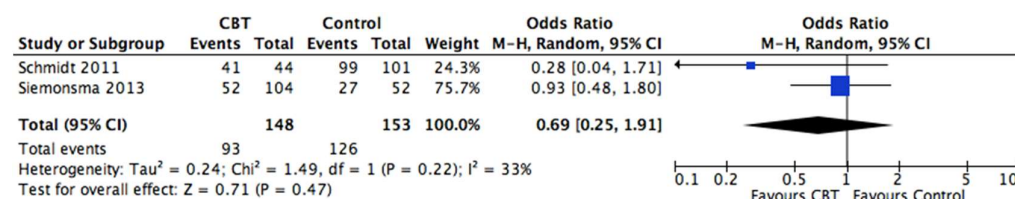
Eight trials with usable data contributed to the meta-analysis of medication use. Six of these studies reported means and standard deviations (or data that was used to derive this information); three referring specifically to mean medication use (Martin et al., 2007; Meng et al., 2014; Sleptsova et al., 2013), and three referring to the cost of medications (Luciano et al., 2013; McCrone et al., 2012; O'Dowd et al., 2006). Most of these trials measured actual costs or counts of all medications taken, regardless of what they were taken for. One study calculated “days of medication use” from participant responses (Martin et al., 2007), and another attempted to predict medication usage and associated costs from dichotomous responses using an algorithm (O'Dowd et al., 2006). The overall effect showed a small reduction in medication use in favour of the intervention: $SMD = -0.12$ (95% CI -0.24 to -0.00); $z = 2.04$, $p = .04$. Heterogeneity was low, at 0%.

Figure 6: Forest plot of comparison 3 - medication use (continuous data)



Two trials contributed event-related data to the medication use outcome, and this was again analysed separately (Schmidt et al., 2011; Siemonsma et al., 2013). Again, the method of measurement of medication use varied. One study measured the number of patients in each group taking pain medication (Siemonsma et al., 2013), whilst the other asked participants to record whether or not they had taken “antidepressants, pain killers or sleep medication” (Schmidt et al., 2011). The overall effect showed no significant difference between groups: OR = 0.69 (95% CI 0.25 to 1.91) $z = 0.71$, $p = 0.47$. Heterogeneity was moderate, at 33%.

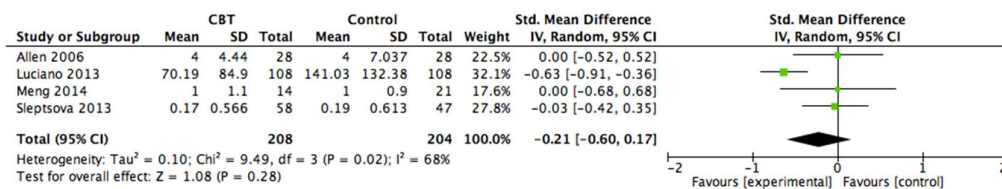
Figure 7: Forest plot of comparison 4 - medication use (dichotomous data)



3.6.3 Medical investigations

Four trials with usable data contributed to the meta-analysis of medical investigations. All of these reported means and standard deviations (or data that was used to derive this information); three referring specifically to mean number of investigations (Allen et al., 2006; Meng et al., 2014; Sleptsova et al., 2013), and one referring to the cost of investigations (Luciano et al., 2013). The overall effect showed no significant reduction between groups: SMD = -0.21 (95% CI -0.60 to 0.17); $z = 1.08$, $p = 0.28$. Heterogeneity was high, at 68%.

Figure 8: Forest plot of comparison 5 – medical investigations (continuous data)



4. Discussion

This review tells three separate but related stories. Firstly, the results of the meta-analysis on the effectiveness of CBT-based interventions in reducing healthcare consumption are presented. Secondly, these results alongside the risk of bias analysis and literature review process give a broader indication of the level and quality of the current body of research on medically unexplained symptoms. Finally, the conclusions and questions drawn from this review contribute to the on-going, wider debate about the clinical usefulness and scientific merits of ‘medically unexplained symptoms’ as a diagnostic category.

4.1 Results of meta-analysis

16 studies contributed data on the effectiveness of CBT-based interventions in reducing healthcare consumption in terms of healthcare contacts ($N = 16$), medication use ($N = 8$) and medical investigations ($N = 4$). Of the 5 separate analyses of continuous and event-related data in each category, the majority showed no effect. The analysis of the effect of treatment on healthcare contacts and resource use (continuous data) had a non-significant, but borderline result ($p = 0.06$). Likewise, the analysis of medication use (continuous data) resulted in a significant, but also borderline effect ($p = 0.04$). These results are in line with the narrative review of the studies that did not provide usable data ($N = 3$), which reported either non-significant or “negligible” reductions in healthcare use. Taken together, these findings suggest that CBT-based treatments are not yet delivering on promises to reduce healthcare consumption in people with medically unexplained symptoms.

Heterogeneity was moderate to high in most analyses, but this was expected due to the non-standardised and diverse methods of measuring healthcare use across studies (for example, the number of visits to a GP versus the cost of a consultation). However, despite the methodological differences, the specific outcome, particularly in the case of healthcare contacts and resource use, was consistent across studies. As a result, and because the scope of this review was to specifically address the question of treatment effects on healthcare use, this heterogeneity does not have serious implications for the interpretation of results.

The one exception to this assumption may be in the analyses of medication consumption. Although statistical heterogeneity was lower in these analyses, the methods of outcome measurement varied in more arbitrary ways and could represent a more significant confounding factor in the analysis. As a result, these effects should be interpreted more cautiously. It is disappointing that medication use was not more robustly measured in some of these studies, or measured at all in half of the trials in this review. Reduction in medication use, particularly in opioids for pain, is often a target outcome for the treatment of chronic pain (which comprises a large proportion of the 'medically unexplained symptoms' category), due to concerns that long-term use can be a source of harm to patients (Ballantyne, 2015; Standard, 2013). Likewise, it was also disconcerting that only three studies specifically measured medical investigations. Overly intrusive, invasive or unnecessary investigations (and associated costs) are also a potential source of harm to patients with medically unexplained symptoms (Price, 2008), and risk strengthening the illness beliefs that these treatments aim to change.

Across the studies reviewed as well as those that were excluded, the quality of the design and data was often questionable. Data on healthcare use (whether as costs, consultations, medications or investigations) should not be difficult to collect either through self-report, or through medical or insurance records. The studies that incorporated or were followed-up with economic analyses arguably provided the

best data, and more studies of this kind are needed. Likewise, it should not be overly arduous to ensure that interventions are delivered by suitably qualified healthcare professionals, yet a number of trials were excluded from this review for that reason. In addition to these findings, there were many concerns with regards to size, blinding of outcome assessments, and handling of incomplete data. The lack of measurement of treatment expectations across the studies was also an interesting finding, particularly given that many theories of medically unexplained symptoms emphasise the role of illness belief in the maintenance of symptoms and disability.

4.2 Status of research on medically unexplained symptoms

This review is in line with previous Cochrane reviews on medically unexplained symptoms, both in finding a small proportion of studies that measured healthcare use (Price et al., 2008), and in finding non-significant or borderline effects (van Dessel et al., 2014). However, the results presented here were less positive than a recent review (Pike et al., 2016) that expanded the search and analysis of a Cochrane review on chronic pain (Williams et al., 2012). It could be that the treatment protocols and research in the field of chronic pain are more developed than they are for the field of medically unexplained symptoms as a broader category, and thus the effectiveness of interventions in reducing healthcare consumption are greater.

One of the most telling findings of this review was that, of the 140 studies on CBT for medically unexplained symptoms examined in the literature search, half of these cited healthcare use as an justification for their research, but 63% of these did not go on to measure it as an outcome. Given that a high level of healthcare use is a potential indicator of poorly treated symptoms, as well as a major driver of increased costs, and a potential source of harm to these patients with medically unexplained symptoms, it is surprising that healthcare use is not more universally measured. In addition, it is disappointing that more robust and standardised ways of measuring

healthcare use are not developed or used in the studies that do report it as an outcome.

4.3 Clinical and research implications

Due to the broad and overlapping nature of the category of medically unexplained symptoms and the difficulties this generates for researchers and treatment providers (highlighted in the introduction to this paper), there are many limitations and questions raised by this review, and by an examination of the wider literature.

Unfortunately, the more that science answers questions about the aetiology and maintenance of specific medically unexplained conditions such as chronic pain, the more that health policy and service commissioning seems to focus on lumping conditions together under the label of 'medically unexplained'. This does not reflect our best scientific understanding, and introduces non-specificity and potential confounding factors in research and clinical practice for these conditions. Using this 'diagnosis' alone, we cannot be confident in either realm that two patients labelled with 'medically unexplained symptoms' suffer from the same condition or different conditions, and we cannot begin to explore what treatments may work best for whom, or the specific factors of an intervention that may induce change.

One of the obvious recommendations from this review is that more studies on treatments for medically unexplained symptoms should measure healthcare use as an outcome, and that healthcare consumption should be measured in more robust and standardised ways. However, it would also be helpful for researchers to unpick the factors that contribute to changes in healthcare utilisation. Patients with medically unexplained symptoms in particular tend to have difficult relationships with healthcare providers, who frequently seem not to believe them or to offer help. As a result, there could conceivably be a number of reasons why a patient might consult healthcare providers less. Improved knowledge and ability to self-manage symptoms could be one explanation, but so could disillusionment with the

healthcare system or turning to alternative forms of healthcare. One study in this review that found a positive effect of the treatment on healthcare use, reported that an element of the intervention was “giving advice about healthcare use” (Martin, 2007). However, without knowing what message the participants took from this, there is no way of knowing if that advice was part of what made the intervention successful and the mechanism behind this effect.

Due to the increasing number of conditions being covered by the label ‘medically unexplained’, there is a risk that studies were missed from this review and in previous reviews. Although the risk for this review in particular was likely reduced by building on the search from the van Dessel et al. review (2014), this is a wider issue for researchers in this field to consider. As the new DSM-5 diagnoses of Somatic Symptom Disorder or Illness Anxiety Disorder no longer have the requirement that symptoms be medically unexplained (American Psychiatric Association, 2013), it is unclear how future research will incorporate this into inclusion criteria in a sensible way (Mayou, 2014; Rief & Martin, 2014; Sharpe, 2013). Likewise, as our scientific understanding of some medically unexplained conditions advances, researchers should be thinking more carefully about how to study these conditions, either together or separately, in a more robust and meaningful way.

Although there currently seems to be a drive in policy and service commissioning for lumping medically unexplained symptoms together, it is clear that more specificity is required to reflect our best scientific knowledge of conditions, and design interventions and studies that will tell us more about what treatments work best for whom. Otherwise, it is likely that the lack of effect found in this review will continue to be found in the future, and this would be a further disservice to people suffering with what is currently described as ‘medically unexplained’.

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Part 2: Empirical Paper

**The impact of a lack of medical explanation for pain, ‘medically
unexplained’ comorbid conditions, and ethnicity on CBT therapists’
judgments of pain and treatment decisions**

Abstract

Background: Judgments of pain are affected by patient and observer factors, and this can have an impact on clinicians' treatment decisions. **Aims:** To investigate the impact of a lack of a medical explanation for pain, 'medically unexplained' comorbid conditions, and ethnicity on CBT therapists' judgments of pain and treatment decisions. **Method:** Participants viewed a computer-generated face displaying an expression of pain, and a written vignette that presented a brief history of the patient. Participants then estimated the severity, exaggeration and minimisation of pain, and the likelihood of pain being caused by a mental or physical health problem. Participants also ranked a number of treatment options from highest priority to lowest priority. **Results:** Small, but significant effects were found for the impact of a lack of a medical explanation for pain and comorbid conditions on CBT therapists' estimations of pain severity and exaggeration. Patients with pain that was presented without a medical explanation or who had a comorbid 'medically unexplained' condition were estimated to be in less pain and more likely to be exaggerating their pain. Consistent with those judgments, these patients were also more likely to be recommended CBT for depression rather than a referral to a specialist service or psychological treatment protocol for pain. Contrary to expectations, no effect on pain judgments was found for the variable of ethnicity, but ethnicity was found to have an impact on treatment decisions. Participants' level of training was also found to have an impact on treatment decisions. **Conclusions:** The impact of comorbid medically unexplained conditions on pain judgments warrants further exploration. Given that recent healthcare initiatives have recommended that more people with medically unexplained symptoms be referred for psychological interventions, more research on CBT therapists' pain judgments is also needed.

1. Introduction

Explaining and treating the functions and malfunctions of the human body has been the perennial task for doctors and scientists since the advent of medicine. Over the course of the last century, increasingly advanced tools and methods have been developed for exploring and examining the body, and many conditions and processes have been explained. However, despite these scientific advances, a recent meta-analysis concluded that up to 49% of patients in primary care still present with at least one symptom for which no adequate medical explanation is found (Haller et al., 2015). For these symptoms, the label 'medically unexplained symptoms' (MUS) has been increasingly used as a diagnosis (Creed et al., 2010; Jutel, 2010; Smith & Dwamena, 2007). This juxtaposition between our high levels of medical sophistication and our continued inability to explain some symptoms and conditions, has made medically unexplained symptoms and their management a contentious issue (Croft, Lewis & Hannaford, 2003; Lynch & Clark, 2005; Merskey, 2005; Williams & Johnson, 2011; Williamson, Buchanan, Quintner & Cohen, 2005).

1.1 History

Prior to the 20th century, most conditions were unexplained and theories about disease aetiology varied in their incorporation of psychological elements. Religious institutions were often viewed as the custodians of the mind, and many scientists and doctors accepted this authority and focused exclusively on the physical body. However, other scientists and much of the lay population recognised the impact of psychosocial factors on physical functioning. Thomas Wright, a philosopher and writer in the early 17th century, theorised that emotional states and thoughts had a direct impact on the body (Brown, 1988). Wright and a number of his colleagues believed that people could die from broken hearts or extreme fear, and that joy, tranquillity and hope could prolong life or effectively treat diseases.

Over the course of the next 200 years, scientific thinking shifted. This change had roots in Cartesian dualism, a philosophy that laid the foundation for thinking

about the 'immaterial' mind and 'material' body as distinct entities (Brown, 1988). Although Descartes' philosophy emphasised the interaction between the mind and body, the idea of a 'mechanical' body that could be objectively observed and measured, gained traction as the scientific tools developed to do so became increasingly advanced. Medicine became highly specialised, and scientists favoured and focused on anatomical, cellular, biochemical and microbial mechanisms of disease.

By the 20th century, dualistic thinking about the mind and body was firmly engrained in scientific thinking. And yet, the phenomenon of interactions between mental and physical states remained obvious to many. The human body did not always seem to behave like a machine responding perfectly to inputs, and doctors continued to notice the impact of emotions and states of mind on physical outcomes (Brown, 1988). It was at this time that the father of psychoanalysis, Sigmund Freud, started a movement that would begin to redress this issue through his descriptions of mental "neuroses" associated with a multitude of physical symptoms that appeared to be generated by those neuroses and cured by talking therapy (Nicholson, Stone & Kanaan, 2009). Freud's theories laid the foundation for the study of the mind – psychology – as a scientific discipline.

Part of this evolution of ideas was the development of 'psychosomatic medicine', or the study of diseases of the mind that seem to manifest in physical symptoms. This began as an extension of Freud's ideas about neuroses, and evolved to encompass all physical symptoms that were deemed to lack an adequate medical explanation. Diagnoses were created to describe these conditions such as 'Somatization Disorder', 'Pain Disorder' and 'Conversion Disorder' (American Psychiatric Association, 1994), and terms such as 'medically unexplained' and 'functional' symptoms also became more widely used (Brown, 2007; Price, 2008; Smith et al., 2007).

The benefit of this new field of study was that it reinforced theories about the impact that mental states can have on the body. Modern research provides good evidence for this notion in general, with clear correlations found between psychological factors such as anxiety or depression and poorer outcomes and higher levels of disability in people who have suffered from serious health conditions such as heart attack (Whooley et al., 2008; Katon et al., 2003) and chronic obstructive pulmonary disease (COPD) (Felker et al., 2010). Patients who experience health anxiety or panic disorder also demonstrate the powerful impact that beliefs and anxiety can have on physical states. However, as our understanding of the interactions between mind and body has become more advanced, it has become clear that the framework put forward by psychosomatic researchers and theorists is too simplistic for many 'medically unexplained' conditions.

For example, the experience of pain was once thought to be only possible in the presence of demonstrable tissue damage. However, further research has shown that this is not the case. Genuine, often debilitating, chronic pain lasting for longer than 3 months and in the absence of observable pathology is a common difficulty (Breivik, Collett, Ventafridda, Cohen & Gallacher, 2006). Most patients who experience this type of pain would meet diagnostic criteria for a somatic disorder (American Psychiatric Association, 1994), and psychosomatic theory posits that this pain is the manifestation of suppressed emotions and conflicts (Nemiah et al., 1976). However, there has been no credible evidence for this theory in relation to chronic pain (Crombez et al., 2009; Shattock et al., 2013). In contrast, the well-established gate-control theory of pain has put forward a credible causal mechanism for pain that involves complex interactions between the brain, spinal cord, and peripheral nervous system (Melzack & Wall, 1965; Moayedi & Davis, 2013). Likewise, a condition such as Chronic Fatigue Syndrome has been widely described as medically unexplained, but research has indicated that it is likely to be caused by complex interactions between autoimmune, adrenal and psychosocial factors

(Hyong et al., 2006). Thus, psychological factors remain only part of the picture for many of these ‘medically unexplained’ conditions, and are not an adequate explanation on their own.

However, despite the lack of evidence, many of the psychosomatic notions about medically unexplained symptoms such as chronic pain remain widely believed both by the public and healthcare professionals (Crombez et al., 2009; Shattock et al., 2013), and are even cited in guidance for both doctors and mental health professionals (Commissioning Support for London, 2010; Department of Health, 2014; Price, 2008). This is perhaps complicated by the fact that we know that stress and mental states are associated with levels of disability and prognosis for many physical health problems, so it is clear that psychosocial factors are not irrelevant to the maintenance and severity of symptoms, whether they are medically explained or not. However, this finding does not mean that mental states are the cause of these symptoms. A person who has had a heart attack may have been at higher risk due to high psychosocial stress and the impact of this on blood pressure, but evidence would not support stress alone as a causal mechanism for heart attack.

However, when symptoms are experienced in the absence of easily observable physical abnormalities, even evidence of impaired function seems to be discounted by doctors and a ‘mental health’ causal explanation is favoured. This is not supported by evidence, and falsely assumes that any symptoms that seem to be unexplained must be caused by a mental health problem. A critical reading of the scientific literature would suggest that there is still much to learn about the human body, and the cause of medically unexplained symptoms and disorders is likely to involve complex, multi-system mechanisms.

1.2 Implications for clinical practice

Whilst this knowledge is theoretically useful and drives future research, it leaves health professionals in a potentially complicated position with patients who complain of symptoms for which no simple medical explanation can be offered.

Particularly in primary care, doctors have limited time for consultations and understandably struggle with patients who present with symptoms for which no observable pathology can be found (Chew-Graham et al., 2008, Mathers et al., 1995; Shattock et al., 2013). For this reason, many guidance documents have been produced to help healthcare professionals more quickly diagnose and manage people with symptoms that appear to be medically unexplained (Chitnis, Dowrick, Byng, Turner & Shiers, 2011; Commissioning Support for London, 2010; Price, 2008).

There are a number of benefits associated with quicker identification of people with 'medically unexplained' conditions or difficulties such as chronic pain (a condition that is still described as unexplained, but, as previously highlighted, has a well-established causal mechanism). Firstly, these patients could be at an increased risk of harm if subjected to overly invasive, costly or unnecessary investigations and treatments (Price, 2008). At the very least, these procedures and treatments are a potential drain on financial and healthcare resources and offer no clear benefits for the patient (Konnopka et al., 2012). At the very worst, unnecessary medical actions can have a negative psychological impact on patients or even cause them physical harm (Lipsitt et al., 2014). Thus, quicker identification of patients and clear guidance on appropriate investigations and treatments could potentially prevent harm to patients.

There has also been growing evidence for the benefit of psychological therapies such as Cognitive Behaviour Therapy (CBT) for patients with a variety of health conditions, including chronic pain and 'medically unexplained' symptoms, as well as 'explained' conditions such as diabetes and chronic obstructive pulmonary disease (Naylor, Parsonage, McDaid, Knapp, Fossey & Galea, 2012; Williams, Eccleston, & Morley, 2012). Often this benefit seems to be in relation to addressing the psychosocial factors that reduce a patients' ability to adapt to symptoms and increase the risk of disability. Thus, early identification of patients who may benefit

from psychological therapy could have significant benefits, and many guidance documents recommend referral to mental health services as a first-line treatment (Commissioning Support for London, 2010; Department of Health, 2011; Department of Health 2014).

However, there are many disadvantages to these guidance documents as well. For example, in their efforts to simplify and expedite clinical decision-making, they often use research that shows correlations between ‘medically unexplained’ symptoms and factors such as comorbid conditions and high levels of distress and disability that seem disproportionate to physical symptoms (Chitnis et al., 2011; Department of Health, 2014). However, this implies psychological causal mechanisms that are unsupported by research (Crombez et al, 2009; Williams & Johnson, 2011).

It also remains a possibility that some patients with symptoms (including pain) that appear to be unexplained, actually have a physical health condition that is difficult to diagnose (Smith & Dwamena, 2007). For example, a condition such as Rheumatoid Arthritis may be misdiagnosed as a ‘medically unexplained’ condition such as a Fibromyalgia, and the resulting delay in treatment could potentially result in increased damage to joints (Fitzcharles & Boulos, 2003). Therefore, guidance that promotes a quicker diagnosis of medically unexplained symptoms in the absence of sufficient medical testing could also be a potential source of harm to patients.

Finally, in the absence of medical tests for symptoms, healthcare providers are effectively being asked to make judgments about the objective severity of patients’ symptoms and the appropriate level of associated distress and functional impact. These judgments are potentially problematic on a number of levels, and will be discussed further in the following section.

1.3 Factors that influence pain judgments

1.3.1 Medical evidence

Healthcare professionals are frequently required to make judgments about the severity of patients' symptoms, whether explained or unexplained, in order to make decisions about symptom management and treatment. For example, a doctor seeing a patient with Rheumatoid Arthritis (an autoimmune condition which causes joint damage and pain through chronic inflammation) may draw on knowledge from research or guidance about the pain caused by the disease, markers of inflammation in blood test results, and observable signs of inflammation in joints such as swelling, redness and warmth (Siemons et al., 2014). These factors aid doctors in making a judgment about the severity of the disease and associated pain, which in turn guides them in weighing up the benefits and risks of increased pain analgesia or further treatments to reduce levels of inflammation.

However, in the case of chronic pain and medically unexplained symptoms, there are often no observable or measurable markers or changes in the body that can be used to inform healthcare professionals' judgments. In addition, guidance documents frequently fail to provide an evidence-based rationale for symptoms such as the gate control theory of pain, and advise healthcare professionals to be vigilant for levels of distress and disability that seem disproportionate to the severity of symptoms (Commissioning Support for London, 2010; Department of Health, 2011; Department of Health 2014; Price, 2008, Chitnis et al., 2011). However, in the absence of tissue damage or concrete evidence of anything being wrong with a patient, and with no framework for understanding how pain can occur under these circumstances, any level of distress or disability will likely seem disproportionate to the symptoms experienced.

Given this picture, it is not surprising that healthcare professionals have been found to underestimate the severity of pain that is not associated with a medical explanation (de Ruddere et al., 2014; de Ruddere, Goubert, Stevens, Williams &

Crombez, 2013; de Ruddere, Goubert, Vervoort, Prkachin & Crombez, 2012; Tait & Chibnall, 1997; Chibnall, Tait & Ross, 1997), even though this does reflect our best understanding of the causal mechanisms and genuine patient experiences of chronic pain (Tait, Chibnall & Kalauokalani, 2009).

Healthcare professionals have also been found to make judgments regarding whether pain is being exaggerated or faked by patients (Kappesser, 2006). This phenomenon seems to arise from an incorrect assumption that, in the absence of verifiable ‘proof’ that pain is real, any expression of pain is likely to be a deviant or exaggerated effort to meet some psychological need (Williams, 2002). As a result, the people who are tasked with judging pain in others are often concerned with “cheater detection”, and ensuring that only those who are deserving receive medical treatment and care for pain (Kappesser, 2006).

However, it has been proposed and demonstrated that people are much more likely to suppress or minimise their pain rather than exaggerate it (Williams, 2000). This is a recognised clinical problem that is a hindrance to adequate pain management. However, the tendency of patients to suppress expressions of pain is not a common stereotype, and frequently seems to be overridden by a desire to detect malingerers and ensure that healthcare resources are only expended on those who ‘deserve’ them.

1.3.2 Patient factors

In addition to the lack of medical evidence for chronic pain and medically unexplained symptoms as well as the current state of guidance and professional knowledge about these conditions, there are many other patient factors that have been shown to have an influence, either consciously or unconsciously, on healthcare providers’ judgments of symptom severity. This is unlikely to be malicious, but rather a genuine effort on the part of the healthcare provider to seek further certainty about the severity of symptoms and aid in weighing up the risks and benefits of treatment (Tait et al., 2009).

Gender

One patient factor that has been shown to affect pain judgments is gender. Multiple studies have found that women are frequently judged to be in less pain than their male counterparts (Anderson et al., 2000; Cleeland et al., 1994; Schäfer, Prkachin, Kaseweter, Williams, 2016; Tait et al., 2009). This bias has also been found to have an impact on treatment decisions, with women receiving less analgesia for pain than men (Chang et al., 2007), and being more likely to have their pain attributed to psychosocial difficulties (Hoffmann & Tarzian, 2001). This finding is perhaps less surprising when guidance on medically unexplained symptoms (which tends to incorporate, rightly or wrongly, chronic pain) indicates that the diagnosis is more common in women than in men (Chitness et al., 2011; Department of Health, 2014). However, it is impossible to know whether this correlation is a result or a driver of this bias in pain judgments. Regardless, underestimation of the severity of pain based on a lack of medical explanation reflects a biased misunderstanding of causal mechanisms and patient experiences of chronic pain.

Ethnicity

Guidance for healthcare professionals also particularly emphasises a higher prevalence of medically unexplained symptoms in people from ethnic minority backgrounds (Commissioning Support for London, 2010; Farooq et al., 1995). The notion that people from ethnic minority backgrounds tend to experience or communicate psychological difficulties through physical symptoms is widely held both by the general public and by healthcare professionals. This theory is backed by poor quality evidence, and has been challenged by current research (Beirens & Fontaine, 2011), but, likely combined with engrained racial biases, it has been shown to have a powerful influence on pain judgments and treatment (Anderson et al., 2009; Balsa & McGuire, 2003; Hausmann et al., 2013, Tait & Chibnall, 2014). For example, in the United States, an extensive study across a variety of settings

found that patients from African and Hispanic ethnic backgrounds received lower doses of pain medication than their white counterparts with the same conditions (Green et al., 2003).

Comorbidity

Finally, guidance also suggests to healthcare professionals (including mental health practitioners) that a comorbid diagnosis of a mental health problem increases the likelihood that a patient's symptoms will be medically unexplained (Chitness et al., 2011, Department of Health, 2014). This recommendation is based on epidemiological studies that indicate that depression is commonly comorbid with chronic pain and medically unexplained symptoms (Bair et al., 2003; Breivik et al., 2006; Miller & Cano, 2009). However, there are multiple problems with this evidence. Notably, depression is likely to be over diagnosed in patients with chronic pain due to overlap between the physical symptoms of depression and the impact of pain on physical functioning (e.g. fatigue, difficulties sleeping) and psychological wellbeing (Williams, 1998, 2007).

There is also a longstanding body of research indicating that healthcare professionals frequently fail to investigate and treat diagnosable health conditions in people with mental health problems (Druss, Rosenheck, Desai, & Perlin, 2002; Viron & Stern, 2010). Studies have shown that this is a pervasive failing across sectors, from primary care to psychiatric settings. Combined with the impact of lifestyle (e.g. increased incidence of smoking) and psychosocial factors on health outcomes (e.g. worse outcomes for cardiovascular and pulmonary disease), this failure to monitor overall health is likely to be at least partially responsible for reduced life expectancy in people with mental health problems (Chesny, Goodwin & Fazel, 2014). As a result, it is disconcerting that guidance for health professionals frequently encourages them to consider a diagnosis of medically unexplained symptoms (and in turn limit medical investigations) in people with comorbid mental health problems.

Patients with medically unexplained symptoms have been shown to more frequently present with a wide range of symptoms and comorbid conditions, and are referred to secondary care for further investigations more often than those who have symptoms that are medically explained (McGorm et al., 2010). For this reason, guidance for healthcare professionals also recommends that symptoms may be more likely to be unexplained when they co-occur alongside other symptoms or conditions (particularly those that are also deemed to be medically unexplained). However, 'explained' conditions that affect multiple body systems such as Rheumatoid Arthritis also produce a wide array of seemingly unrelated symptoms that could be easy to misdiagnose as medically unexplained (Fitzcharles & Boulos, 2003). Thus, as for people with mental health problems, patients with multiple symptoms are also probably at risk of being dismissed, misdiagnosed, or ineffectively treated.

1.4 Impact on patients

The impact on patients from these frequently biased beliefs about chronic pain and medically unexplained symptoms is immense. Not only are their symptoms judged to be less serious and potentially under-treated (as highlighted above), but research has shown that patients frequently feel disbelieved and dismissed by healthcare providers, and this increases their levels of distress (Nettleton, 1982; Rhodes et al., 1999; Sim & Madden, 1982; Stone et al., 2002). This is damaging to the doctor-patient relationship, and probably increases the risk of inadequate symptom management and higher levels of impairment and disability.

1.6 Implications for psychological therapies

As stated earlier, there is growing evidence for the effectiveness of psychology therapies such as Cognitive Behaviour Therapy (CBT) in the management and treatment of people with a number of health problems, including chronic pain and medically unexplained symptoms. However, there are a variety of different elements associated with CBT treatment protocols, and much is still left to learn in

determining which aspects of treatment produce change for whom, and the mechanisms that drive these changes (Brown, 2007; Rief & Broadbent, 2007; Williams, Eccleston, & Morley, 2012).

For example, one theory of chronic pain or medically unexplained symptoms emphasises the role of unhelpful beliefs in prompting patients to reduce their activity levels, which in turn leads to physical deconditioning, increased symptoms such as pain and fatigue, and higher levels of functional impairment (Deary, Chalder & Sharpe, 2006; Rief & Nanke, 1999). A CBT treatment protocol based on this model may exclusively use techniques for challenging unhelpful beliefs (e.g. cognitive restructuring, behavioural experiments), or techniques for increasing physical activity (e.g. behavioural activation, graded exercise). In comparison, another theory emphasises the role of a maladaptation or inflexible response to symptoms, which leads to increased levels of distress and increases the likelihood of mood or anxiety disorders and higher levels of disability (Yu & McCracken, 2016). Treatment protocols based on this model may employ practical problem-solving or coping strategies (e.g. pacing of physical activities in order to avoid over-exertion), relaxation strategies, or techniques to increase acceptance and adaptation to symptoms (e.g. mindfulness, cognitive restructuring).

However, perhaps due to the relative lack of research showing what works best for whom (Williams et al., 2012), there are few available treatment protocols for chronic pain that are suitable for utilisation in primary care (Lewis, 2013). Research has also shown that there may be a lack of specialist training for CBT therapists and psychologists in the treatment of health conditions in general, let alone in the comparatively complex area of chronic pain and medically unexplained symptoms (Belar et al., 2001; Rozensky, 2014). Perhaps for these reasons, preliminary research has shown that primary care CBT therapists in the UK lack knowledge and confidence in treating people with medically unexplained symptoms and chronic pain (Lewis, 2013).

Previous research on healthcare professionals' judgments of pain severity has focused exclusively on medical students, doctors and nurses (de Ruddere et al., 2014; de Ruddere, Goubert, Stevens, Williams & Crombez, 2013; de Ruddere, Goubert, Vervoort, Prkachin & Crombez, 2012; Tait & Chibnall, 1994, 1997). These judgments are likely also to be a part of the process with mental health practitioners as well, particularly given that they will likely need to assess for whether a patient has a mental health problem that would require a particular treatment (e.g. health anxiety, depression), or a problem with coping skills and adaptation to symptoms that would likely require a different approach.

However, there seems to be no research that has investigated the pain judgments of mental health practitioners, so it is unclear how these may differ (or not) from those of medical staff. The majority of CBT therapists and psychologists will have a non-medical educational background, and less medical knowledge may lead to more biased judgments of pain, particularly when a referral from a medical practitioner may provide reassurance that nothing is physical wrong with a patient, or that no further medical testing is required. This is particularly the case when, rather than psychological therapy being an integrated treatment with the aim of helping patients live better with pain from the start, it is offered as a 'last resort' option when all medical attempts at managing pain have failed. At this late stage in the process, there can be a tendency to dismiss pain and focus on the psychosocial factors that contribute the experience of pain, and this can leave the patient feeling blamed and less amenable to engaging in psychological interventions.

In addition, given that psychosomatic medicine is a field of psychology, mental health practitioners and psychologists may be more familiar with psychosomatic theories about 'medically unexplained' symptoms and pain. Mental health practitioners are also trained to attend more to psychosocial factors and are possibly more likely to see difficulties through the lens of mental health. As a result, mental health practitioners may be more likely to believe that symptoms without medical

explanations are indicators of a mental health problem, and may therefore be more likely to disregard or judge physical symptoms to be less serious. These judgments could also lead mental health practitioners to choose different treatments for people with 'medically unexplained' symptoms and pain than they would for people who have medical explanations for their symptoms.

Beyond these practitioner-related factors, there are also patient factors that could impact on the effectiveness of psychological therapies for medically unexplained symptoms and chronic pain. Patients with 'medically unexplained' symptoms often fear and feel resentful of having their symptoms disregarded and attributed to mental health problems (Sim et al., 1982; Stone et al., 2002), and interpret referral to mental health services as an indication of this. Given that these difficulties are combined with potential practitioner-related factors (e.g. lack of training and treatment protocols for pain and medically unexplained symptoms, biased beliefs, and psychosomatic theoretical stance), it is unsurprising that there seems to have been limited engagement from patients with chronic pain in psychological therapies.

Governments are understandably keen to reduce the toll of chronic pain and medically unexplained symptoms on patients and healthcare resources. In the UK in particular, government initiatives have encouraged referral of more people with these difficulties to primary care psychological therapies services (Commissioning Support for London, 2010; Department of Health, 2011; Department of Health, 2014; Rozensky, 2014). However, without addressing the issues raised here, in many cases it is unlikely that patients will be effectively treated. Healthcare providers and governments aim to have patients engage in and benefit from psychological therapies, but this will likely require a certain knowledge, understanding and theoretical stance from therapists that many working in primary care are unlikely to have at this stage. As a result, the difficulties that are still rampant in medical settings are likely to perpetuate in psychological therapies settings as well.

1.7 Rationale for current study

As outlined above, previous studies have investigated the effect of medical explanations provided to clinicians and others (or the lack thereof) on their judgments of pain, including estimations of pain severity and the likelihood that pain is exaggerated or minimised (Chibnall, Tait, & Ross, 1997; de Ruddere et al., 2014, 2013; Tait & Chibnall, 1994). However, participants in these studies were primarily from medical backgrounds. As far as is known, no research of this kind has been done with mental health professionals, though the question is particularly relevant in light of recent government initiatives aiming to offer psychological therapies as a primary treatment for medically unexplained symptoms and chronic pain (Commissioning Support for London, 2010; Department of Health, 2011; Department of Health, 2014). This is also the case for studies on the impact of ethnicity on pain judgments and treatment decisions.

There also do not appear to be any studies that have investigated the effect of information given about comorbid medically unexplained conditions on judgments of pain in others. As previously highlighted, comorbid conditions (and particularly those that are considered medically unexplained) have been cited in guidance for medical practitioners in identifying and diagnosing medically unexplained symptoms, although this recommendation supports a mental health causal mechanism that is not supported by science.

Finally, preliminary research has identified that many primary care CBT therapists lack training in understanding or treating medically unexplained symptoms or chronic pain, and this is cited as having a potential impact on competency (Lewis, 2013; Rozensky, 2014). A lack of training could limit practitioners' understanding of the symptoms of medically unexplained symptoms and have an impact on treatment decisions. In turn, this lack of knowledge could reduce the effectiveness of psychological therapy for medically unexplained symptoms and chronic pain.

This study therefore aimed to investigate the factors that impact on mental health professionals' judgments of pain and treatment decisions. The following factors were explored: 1) the medical explanation or lack of explanation given for pain, 2) the presence or absence of a comorbid medically unexplained condition, 3) ethnicity and 4) levels of training in medically unexplained symptoms, chronic pain or long-term conditions. The following judgments of pain were also investigated: 1) estimates of pain severity, 2) estimates of pain exaggeration, 3) estimates of pain minimisation, and 4) estimates of pain being caused by a mental or physical health problem.

2. Research questions and hypotheses

2.1 Research Question 1: What is the impact of a lack of a medical explanation for pain on CBT therapists' judgments of pain (estimates of pain severity, exaggeration and minimisation)?

Hypotheses: Pain presented without a medical explanation, by contrast with pain presented with a common medical explanation, will be estimated by participants as: 1a) less severe, 1b) more exaggerated, and 1c) less minimised.

2.2 Research Question 2: What is the impact of a 'medically unexplained' comorbidity on CBT therapists' judgments of pain (estimates of pain severity, exaggeration or minimisation, and of the likelihood that pain is caused by mental health problem)?

Hypotheses: Medically explained and unexplained pain that is accompanied by a comorbid medically unexplained condition, by contrast with pain with no comorbid condition, will be estimated by participants as: 2a) less severe, 2b) more exaggerated, 2c) less minimised, and 2d) more likely to be caused by a mental health problem.

2.3 Research Question 3: What is the impact of ethnicity on CBT therapists' judgments of pain (estimates of pain severity, exaggeration or minimisation, and of the likelihood that pain is caused by mental health problem)?

Hypotheses: Asian patients, by contrast with white patients, will have their pain estimated by participants as: 3a) less severe, 3b) more exaggerated, 3c) less minimised, and 3d) more likely to be caused by a mental health problem.

2.4 Research Question 4: Do these variables (ethnicity and the presence or absence of a medical explanation for pain or comorbid medically unexplained condition) interact to affect CBT therapists' judgments of pain?

Hypotheses: There will be interactions between these variables, so that medically unexplained pain, accompanied by a comorbid medically unexplained condition and experienced by Asian patients, will be estimated by participants as: 4a) the least severe, 4b) the most exaggerated, 4c) the least minimised, and 4d) the most likely to be caused by a mental health problem.

2.5 Research Question 5: Are CBT therapists' treatment decisions affected by the patient's ethnicity or the presence or absence of a medical explanation for pain or medically unexplained comorbidity?

Hypotheses: Participants will prioritise treatment for depression over treatment for pain when: 5a) pain is presented without a medical explanation (by contrast with pain presented with a common medical explanation), 5b) medically explained or unexplained pain is accompanied by a comorbid medically unexplained condition (by contrast with pain accompanied by no comorbid condition), and 5c) pain is experienced by Asian patients (by contrast with white patients).

Research Question 6: Are CBT therapists' treatment decisions affected by the amount of training that they have received in chronic pain, long-term conditions, or medically unexplained symptoms?

Hypothesis: 6a) CBT therapists without training in chronic pain, medically unexplained symptoms, or long-term conditions, by contrast with those who have had training in these areas, will prioritise treatment for depression over treatment for pain.

3. Method

3.1 Setting and participants

This study was conducted using internet-based written vignettes, computer-generated faces, and questions. Participants were qualified CBT therapists working in primary care mental health services in the UK. They were recruited by email either directly through their service managers or indirectly through social media and emails from CBT education providers. Please see Appendix 10 for a copy of the recruitment email, and Appendix 11 for a copy of the online information sheet and consent form.

3.2 Ethics

Ethical approval was obtained for this study through University College London (project ID: 2584/001). For recruitment directly through the National Health Service (NHS), sponsorship was obtained through University College London and individual approval was granted by nine primary care psychological therapies services under six different NHS trusts (West London Mental Health Trust, East London NHS Foundation Trust, Central and Northwest London NHS Foundation Trust, The Whittington Health NHS Trust, North East London NHS Foundation Trust, and Barnet, Enfield and Haringey Mental Health Trust). See Appendices 2 – 9 for ethical approval letters.

3.3 Design

On accessing the Internet-based study, participants were assigned to see vignettes of either Asian or white patients. Participants were then assigned three vignettes that included three categories of medical information about the patient:

- 1) Chronic pain presented with a common medical explanation and with no comorbid conditions (hereafter referred to as “medically explained pain only”)
- 2) Chronic pain presented as medically unexplained and with no comorbid conditions (hereafter referred to as “medically unexplained pain only”)
- 3) Chronic pain presented as either medically explained or unexplained, with a comorbid medically unexplained condition, Chronic Fatigue Syndrome (hereafter referred to as “comorbid CFS with explained/unexplained pain”).

A 3 (‘medical information’: medically explained pain only, medically unexplained pain only, comorbid CFS with explained/unexplained pain) x 2 (‘ethnicity’: white or Asian) mixed design was therefore used. The variable of medical information was a within-subjects variable, and the variable of ethnicity was a between-subjects variable.

3.3.1 Survey software and randomisation

The Qualtrics software (Qualtrics, Provo, UT) was used to host the study on the internet and to provide the computerised, automated randomisation. Block randomisation procedures were not used. In order to protect participant confidentiality, Qualtrics was also configured to ensure that no identifying information was gathered from participants.

3.3.2 Online questions format

The online questions consisted of two main parts: the experiment proper and a survey of specialist training in chronic pain or MUS. The survey was given after the experimental questions in order to avoid alerting the participants to the aims of the study, and was analysed separately. Appendix 14 shows the internet-based questions as they appeared to participants.

The first set of dependent variables were related to participants' judgments of pain for each patient: 1) estimates of pain severity, 2) estimates of pain exaggeration, 3) estimated of pain minimisation, 4) estimates of the likelihood that pain was caused by a mental health problem, and 5) estimates of the likelihood that pain was caused by a physical health problem. Responses were given using numerical scales from 0 to 10. For pain severity estimates, the scale was anchored at 0 with "no pain" and at 10 with "worst possible pain". For estimates of pain exaggeration or minimisation, the scale was anchored at 0 with "no exaggeration/minimisation" and at 10 with "strong exaggeration/minimisation". For estimates of the likelihood that pain was caused by a mental or physical health problem, the scale was anchored at 0 with "very unlikely" and at 10 with "very likely". As previously highlighted, these questions were based on previous research on pain judgments.

The second set of dependent variables was: participants' decisions regarding which treatment options to prioritise (i.e. referral to specialist services for pain, CBT for depression, or psychological treatment protocol for pain). These were shown in a list format and participants were asked to place them in order of priority. There was also an option for participants to indicate that a particular option was unfamiliar to them.

3.3.3 Vignette design and allocation

Computer-generated patient faces and written vignettes were used to simulate the first meeting with a patient experiencing chronic pain and low mood, who was either white or Asian, had medically explained or unexplained pain, and either had comorbid CFS or no comorbid condition.

As highlighted in the introduction to this paper, previous research has found gender effects on pain judgments, with female patients more likely to have their pain underestimated and attributed to a mental health problem. As a result, it was

important to control for this factor, and only female patients were used in the vignettes for this study.

The two independent variables (i.e. medical information and ethnicity) were manipulated through either the computer-generated faces or written vignettes. FaceGen software (Singular Inversions, 2014) was used to produce computer-generated images of patient faces, and FACSGen 2.0 software (Swiss Centre for Affective Sciences, 2010; Roesch et al., 2010) was used to manipulate the expressions of these faces. These images began with a photo of an actual person, which was then converted into a computer-generated face. This computer-generated prototype face was then manipulated to express a particular experience or emotion, in this case pain. The face could then be replicated, without altering the expression, in different genders, ages and ethnicities. For this study, the faces were used to manipulate the ethnicity of the person in the vignette, and were also made to display facial expressions of pain. Appendix 12 shows the faces and expressions that were created for this study.

The FaceGen and FACSGen software was made available by Dr Eva Krumhuber at University College London, who also generated the initial prototype faces and pain expressions (along with a research student). Photo editing software was then used to add hair and clothing. The pain expressions were also validated by Dr Eva Krumhuber (along with a research student), meaning that the expressions used in this study were most consistently recognised as expressions of pain. As actual photos of white and Asian people were used to create the computer-generated faces, it was assumed that the faces would also be valid stimuli for the variable of ethnicity. However, the ethnicities of the computer-generated faces were not validated. Consequently, it is not known whether these faces would be consistently recognised as being from the intended ethnic background.

One advantage of using this technique was that it increased the ecological validity of the study by showing patient faces with expressions that indicated the

experience of pain, rather than simply a written vignette. Equally, this software allowed the same expressions to be used across conditions. In other words, while the ethnicity of a patient changed, the facial expression remained the same (Roesch et al., 2010). This level of control over facial expressions would not have been possible with other commonly used methods, such as the use of actors of different ethnicities to portray patients with pain.

Four different written vignettes and six different computer-generated faces were produced. These vignettes and faces were randomly combined using the Qualtrics survey software, so that each vignette had an equal chance of being paired with each face. This resulted in 32 possible configurations. All vignettes showed a female patient presenting at assessment, reporting chronic pain and low mood that developed at approximately the same time. The report included either a common 'medical' explanation for pain (i.e. "slipped disk" or "compressed nerve") or it implied the lack of a medical explanation by reporting that "scans" of the patient's back found "no abnormalities". The report also included either comorbid CFS or no comorbid conditions. Appendix 13 shows the written vignettes that were used for this study.

Of the 32 combinations of written vignettes and faces, each participant was allocated to three as follows: on accessing the online questions, participants were randomly assigned (using the Qualtrics survey software) either to see patients from a white or Asian background. They were then shown one vignette of a patient with medically explained pain only, and one with medically unexplained pain only. Finally, they were assigned a third vignette of a patient with comorbid CFS that was randomly (using Qualtrics) reported alongside either medically explained or unexplained pain.

3.4 Power Analysis

The power analysis for this study was informed by prior work on judgments of pain through the use of vignettes (de Ruddere et al., 2012). This study found a

Cohen's D effect size of 0.5 for pain estimations, which was converted to a F effect size of 0.25. The "G*Power 3.1" program (Erdfelder, Faul, & Buchner, 1996) was used for the power calculation (alpha, 0.05; desired power, 0.80; estimated correlation among repeated measures, 0.5). Due to the mixed within-between design used in this study, the required sample size varied. In order to detect effects for the within-subjects variable of medical information, 20 participants were required. Up to 76 participants were required to detect the effect for the between-subjects variable of ethnicity.

3.5 Analysis

3.5.1 Pain judgments

Judgments of pain and the independent variables of medical information and ethnicity (and planned contrasts and interactions of these as stated in hypotheses) were tested using two-way mixed ANOVAs.

3.5.2 ANOVA assumptions

The two-way mixed ANOVA involves three assumptions about study design: 1) dependent variables are measured at the continuous level (interval or ratio), 2) there is one between-subjects, categorical independent variable with at least two categories, and 3) there is one within-subjects, categorical independent variable with at least two categories (Laerd Statistics, 2015a). Numerical scales, when possible answers are formulated symmetrically (i.e. "very unlikely" to "very likely") as they were in this study, can be treated as an interval scale (Carifio & Perla, 2007). Therefore, all three of these assumptions regarding study design were met.

The two-way mixed ANOVA also involves five assumptions about the data analysed: 1) no significant outliers, 2) normal distribution, 3) homogeneity of variances, 4) homogeneity of covariances, and 5) assumption of sphericity (Laerd Statistics, 2015a). It is not uncommon for data to violate one or more of these assumptions, so each will be discussed in more detail.

All data had some outliers, although none of these were extreme. These outliers were always included in the analysis because there was no good reason to remove them, and because ANOVAs are considered to be robust to handling outliers (Laerd Statistics, 2015a).

For all variables, the assumption of homogeneity of covariances, as assessed by Box's test of equality of covariance matrices ($p > .05$), was met. For estimations of pain severity and exaggeration, the assumption of homogeneity of variances, as assessed by Levene's test ($p > .05$), was also met. Levene's test was failed by one category of the medical information variable ($p = .031$) for the analysis of estimates of pain minimisation. However, when group sample sizes are approximately equal, ANOVAs are considered to be somewhat robust to heterogeneity of variance (Laerd Statistics, 2015a). The decision was therefore made to proceed with that analysis.

As is commonly found in psychological tests using numerical scales, none of the data associated with the variable of pain judgments were normally distributed, as assessed by the Kolmogorov-Smirnov test ($p < .05$). All attempts to transform the data were unsuccessful. ANOVAs are considered to be robust to deviations from normality, particularly in cases where the sample sizes are not small, and the groups are similarly skewed (Laerd Statistics, 2015a). Estimates of pain severity were all negatively skewed (values ranging from $-.576$ to $-.672$), estimates of pain exaggeration were all positively skewed (values ranging from 1.144 to 1.684), and estimates of pain minimisation were also all positively skewed (values ranging from 1.024 to 1.418). These variables therefore complied with above guidelines, and the associated analyses are considered to be robust.

In contrast, estimates of the likelihood that pain was caused by a mental or physical health problem were not similarly skewed. Estimates of pain being caused by a mental health problem were both positively and negatively skewed, with values ranging from $-.127$ to 1.073 . Likewise, estimates of the pain being caused by a physical health problem had skew values ranging from $-.975$ to $.986$. As there were

no non-parametric equivalents to test the two-way mixed interactions, the decision was made to proceed with the analysis. However, these results should be interpreted with caution.

Planned interactions between the variables of medical information and ethnicity were also tested through two-way mixed ANOVAs. For all variables, the assumption of sphericity was met for the two-way interaction, as assessed by Mauchly's test ($p > .05$).

3.5.3 Treatment decisions – impact of medical information and ethnicity

A three-way loglinear analysis was used to determine whether there were any associations between the three categorical variables of ethnicity, medical information, and participants' treatment decisions. For this analysis, the hypothesis specifically related to whether participants would prioritise treatments for depression (i.e. CBT for depression) or pain (i.e. either a referral to specialist services for pain or the use of a psychological treatment protocol for pain). The data associated with participants' treatment decisions was converted into a categorical variable with three categories: 1) CBT for depression, 2) referral to specialist services for pain, 3) psychological treatment protocol for pain. Data associated with all three categorical variables was then organised into combined frequencies for each variable category and every possible combination of these (shown in Tables 7 and 8).

In the original design of this study, participants were given five treatment options to choose from: 1) CBT treatment for depression, 2) referral to a health psychology service, 3) referral to a pain management service, 4) contact GP for more information, and 5) psychological treatment for pain. However, when it came to analysing these treatment decisions and what they meant for patients, it became clear that it was not meaningful in this study to look at the option of contacting the GP for more information. Likewise, it was more useful to combine the options of health psychology and pain management services, in order to gain a full picture of when CBT therapists would prefer to refer to specialist services. It was therefore

decided to eliminate the option of contacting the GP and condense the options of referral to health psychology and pain management services into one option. This reduced the specificity of the analysis, so that it is not possible to determine whether CBT therapists preferred to refer to health psychology or pain management services. However, as it is not known whether these services were available in participants' areas, that information would have had limited usefulness in this study.

The purpose of this analysis was to find the simplest model that fit the data. Therefore, a hierarchical, unsaturated model was chosen using the SPSS hierarchical loglinear model selection procedure, and the backwards elimination stepwise procedure (Laerd Statistics, 2015b). This allowed SPSS to remove the least statistically significant effects and determine the highest-order effects and main interactions (i.e. those that are most predictive of the cell frequencies in the data). This process produced a model that included all main effects and two, two-way associations between ethnicity and treatment priorities, and medical information and treatment priorities.

Loglinear analysis involves three assumptions: 1) that all cell counts are greater than one and 80% are greater than five, 2) there are no outliers, and 3) the residuals are approximately normally distributed (Laerd Statistics, 2015b). In this analysis, there were 321 responses, with all 18 cells having greater than five expected frequencies, no outliers and approximately normally distributed adjusted residuals (as assessed by a Q-Q plot).

3.5.4 Treatment decisions – impact of participants' level of training

A chi-square test for association was conducted to determine whether there were associations between the two categorical variables of training (i.e. level of participants' training in medically unexplained symptoms, chronic pain, or long-term conditions) and treatment decisions. The variable of training had three categories: 1) no training, 2) training, duration less than 1 day, 3) training, duration more than 1 day.

As with the previous analysis, data associated with participants' treatment decisions was converted to a categorical form based on the responses given. The variable of treatment decisions was again split into three categories: 1) CBT for depression, 2) referral to specialist services for pain, 3) psychological treatment protocol for pain. Data associated with all three categorical variables was then organised into combined frequencies for each variable category and every possible combination of these (shown in Table 11).

The chi-square test for association involves three assumptions: 1) there are two categorical variables, 2) there is independence of observations (i.e. groups are not related), and 3) all cell frequencies are greater than five (Laerd Statistics, 2016). All three of these assumptions were met for this analysis.

4. Results

4.1 Participants

4.1.1 Participant recruitment and attrition rates

107 participants completed the online questions. A further 32 participants either did not complete the questions fully (N = 21), were ineligible to participate due to lacking a qualification in CBT (N = 3), or did not provide full consent (N = 8). The majority of participants were recruited through social media or emails from CBT education providers (N = 91). The remaining participants (N = 48) were recruited directly from nine NHS primary care psychological therapy services. The original plan for this study was to recruit exclusively from these NHS services, but recruitment was much lower than anticipated on the basis of discussions with service managers.

4.1.2 Group allocation

46 participants were randomly assigned to view three vignettes associated with white patients, and 61 to view three vignettes associated with Asian patients. After viewing the first two vignettes (one with medically explained pain only and the

other with medically unexplained pain only), participants were then randomly allocated a third vignette of a patient in the same ethnic group with comorbid CFS associated with either medically unexplained pain (N = 56) or medically explained pain (N = 51).

4.1.3 Participant baseline characteristics and survey of training

In order to preserve the confidentiality of participants, limited information was gathered about their ethnic background, educational background, and levels of training in chronic pain, MUS or long-term conditions. Tables 1 and 2 provide details of the demographic characteristics and training levels of participants.

The majority of participants were white/white British and described their education as non-medical. Most participants reported that they had received some amount of training in MUS or chronic pain, although half of these stated that it was of 1 day or less duration. Approximately half of these participants reported that they had received training in MUS or chronic pain either exclusively or partly through their core CBT training.

Table 1. Demographic information for participants

	n (N = 107)	%
Ethnicity		
White/White British	88	82
Asian/Asian British	7	7
Black/Black British	3	3
Mixed/Multiple	5	5
Education background		
Non-medical	86	80
Medical (i.e. nursing)	21	20

Table 2. Training information for participants

	n (N = 107)	%
Amount of training in medically unexplained conditions, long-term conditions or chronic pain		
No training	14	13
1 day or less of training	46	43
More than 1 day of training	47	44
Source of training in medically unexplained conditions, long-term conditions or chronic pain		
Part of core CBT training	31	30
Additional training	53	51
Both	20	19

4.2 The impact of medical information on pain judgments

A two-way ANOVA was used to investigate the impact of medical information on pain judgments. Sections 3.5.1 and 3.5.2 provide more detailed information on the categories of these variables and the fit of the data to the assumptions for ANOVAs.

Table 3 provides the means (standard errors), F ratio, and p values for differences between medical information groups for each dependent variable associated with pain judgments. Overall, there were significant differences between groups for estimations of pain severity (*hypotheses 1a and 2a*) and exaggeration (*hypothesis 1b and 2b*), but no significant differences between groups for estimations of pain minimisation (*hypothesis 1c and 2c*). In addition, there were significant differences between groups for estimations of the likelihood that pain was caused by a mental or physical health problem (*hypothesis 2d*).

Table 4 shows the mean differences (standard errors), p values, and 95% confidence intervals for the pairwise comparisons between conditions. These pairwise comparisons were used to answer research questions 1 and 2, and will be discussed separately.

Table 3. Means (standard errors), *F* ratios, and *p* values, for the effect of medical information on pain judgments

	Medically explained pain only	Medically unexplained pain only	Comorbid CFS with explained/unexplained pain	<i>F</i> (2, 210)	<i>p</i>
<u>Questions</u>					
"How severe do you think [the patient's] pain is?" <i>Scale from 0 (no pain) to 10 (worst possible pain)</i>	8.3 (1.1)	7.8 (1.4)	7.7 (1.7)	10.02	<.0005
"How much do you think [the patient] is exaggerating her pain?" <i>Scale from 0 (no exaggeration) to 10 (strong exaggeration)</i>	2.0 (1.5)	2.7 (2.2)	2.9 (2.3)	14.41	<.0005
"How much do you think [the patient] is minimising her pain?" <i>Scale from 0 (no minimisation) to 10 (strong minimisation)</i>	2.6 (2.0)	2.3 (1.9)	2.4 (1.7)	1.36	.260
"How likely is it that [the patient's] pain is caused by a □ mental health problem?" <i>Scale from 0 (very unlikely) to 10 (very likely)</i>	3.6 (2.1)	5.5 (1.9)	5.8 (2.2)	50.96	<.0005
"How likely is it that [the patient's] pain is caused by a □ physical health problem?" <i>Scale from 0 (very unlikely) to 10 (very likely)</i>	8.7 (1.9)	6.3 (1.7)	6.6 (2.3)	72.12	<.0005
Note: values in bold denote significance (<i>p</i> < .05)					

Table 4. Pairwise comparisons (mean difference [standard error], p value, and 95% confidence intervals) of the effect of medical information on pain judgments.

		Mean Difference (standard error)	<i>p</i>	95% Confidence Interval	
				Lower Bound	Upper Bound
“How severe do you think [the patient’s] pain is?” <i>Scale from 0 (no pain) to 10 (worst possible pain)</i>					
Comorbid CFS with explained / unexplained pain	Medically unexplained pain only	-.152 (.158)	.340		
Comorbid CFS with explained / unexplained pain	Medically explained pain only	-.648 (.153)	<.0005	-.952	-.344
Medically unexplained pain only	Medically explained pain only	-.496 (.142)	.001	-.778	-.214
“How much do you think [the patient] is exaggerating her pain?” <i>Scale from 0 (no exaggeration) to 10 (strong exaggeration)</i>					
Comorbid CFS with explained / unexplained pain	Medically unexplained pain only	.207 (.193)	.287		
Comorbid CFS with explained / unexplained pain	Medically explained pain only	.931 (.181)	<.0005	.573	1.290
Medically unexplained pain only	Medically explained pain only	.725 (.172)	<.0005	.384	1.065
“How likely is it that [the patient’s] pain is caused by a □ mental health problem?” <i>Scale from 0 (very unlikely) to 10 (very likely)</i>					
Comorbid CFS with explained / unexplained pain	Medically unexplained pain only	.275 (.245)	.265		
Comorbid CFS with explained / unexplained pain	Medically explained pain only	2.266 (.273)	<.0005	1.725	2.807
Medically unexplained pain only	Medically explained pain only	1.991 (.213)	<.0005	1.568	2.414
“How likely is it that [the patient’s] pain is caused by a □ physical health problem?” <i>Scale from 0 (very unlikely) to 10 (very likely)</i>					
Comorbid CFS with explained / unexplained pain	Medically unexplained pain only	-.383 (.275)	.168		
Comorbid CFS with explained / unexplained pain	Medically explained pain only	-2.104 (.276)	<.0005	-2.651	-1.557
Medically unexplained pain only	Medically explained pain only	-2.487 (.215)	<.0005	-2.912	-2.061

Note: values in bold denote significance (*p* < .05)

Research Question 1: What is the impact of a lack of a medical explanation for pain on CBT therapists' estimations of pain severity, and estimations of the likelihood that pain is exaggerated or minimised?

Overall, estimates of the severity of patients' pain were high across categories. However, pain that was presented with a common medical explanation was estimated as significantly more severe than medically unexplained pain (mean difference = 0.496, $p = .001$, $d = 0.402$ [medium effect]) (Cohen, 1992). This means that, on average, pain presented as medically unexplained was estimated to be half a point less severe on a scale from 0 (no pain) – 10 (worst possible pain) than pain that was presented with a common medical explanation (*hypothesis 1a*).

Likewise, medically explained pain was estimated to be significantly less exaggerated than medically unexplained pain (mean difference = -.725, $p < .0005$, $d = -0.383$ (medium effect), although ratings overall were low (*hypothesis 2a*).

Medically unexplained pain was also estimated to be significantly more likely to be caused by mental health problem and significantly less likely to be caused by a physical health problem than medically explained pain.

4.3 Impact of comorbidity on pain judgments

Research Question 2: What is the impact of a medically unexplained comorbid condition on CBT therapists' estimates of pain severity, exaggeration or minimisation, and estimations of the likelihood that pain is caused by mental health problem?

When compared with medically explained pain only, both explained and unexplained pain were estimated to be less severe when accompanied by comorbid CFS (mean difference = -.648, $p < .0005$, $d = -0.438$ [medium effect]) (*hypothesis 2a*). This difference in estimates of pain severity was similar to the previous analysis, meaning that pain accompanied by comorbid CFS as well as pain presented without a medical explanation were judged to be similarly less severe (by about half a point on a scale from 0 (no pain) – 10 (worst possible pain) than pain

that was presented with a common medical explanation and no comorbid conditions.

Both explained and unexplained pain were also estimated to be more exaggerated when accompanied by comorbid CFS (mean difference = .931, $p < .0005$, $d = 0.466$ [medium effect]) (*hypothesis 2b*). This was a higher difference than the previous analysis, with pain accompanied by comorbid CFS being judged as more exaggerated by nearly 1 point higher on a scale from 0 (no exaggeration) to 10 (strong exaggeration) than pain that was presented with a common medical explanation and no comorbid conditions.

In addition, explained or unexplained pain that was accompanied by a MUS comorbid condition was estimated to be significantly more likely to be caused by a mental health problem (mean difference = 2.266, $p < .0005$, $d = 1.034$ [large effect]), and significantly less likely to be caused by a physical health problem (mean difference = -2.104, $p < .0005$, $d = -1.024$ [large effect]) (*hypothesis 2d*). This was a strong effect, with over a 2 point difference in scores on a scale from 0 (very unlikely) to 10 (very likely).

Although not a significant difference, the directions of effects were the same when explained/unexplained pain with comorbid CFS was compared with medically unexplained pain only (Table 4).

4.4 Impact of ethnicity on pain judgments

Research Question 3: What is the impact of ethnicity on CBT therapists' estimations of pain severity, exaggeration or minimisation, and estimations of the likelihood that pain is caused by mental health problem?

There was no significant effect of ethnicity on estimations of pain severity (*hypothesis 2a*), exaggeration of pain (*hypothesis 2b*), or minimisation of pain (*hypothesis 2c*), or on the estimations of the likelihood that pain was caused by a mental or physical health problem (*hypothesis 2d*). Table 5 provides the means (standard errors), F ratios, and p values for these differences.

In line with the previous findings, the mean estimates of pain severity were high, and mean estimates of pain exaggeration and minimisation were low. Although there were no significant differences, there was a trend (in line with hypotheses) for White patients, in contrast with Asian patients, to have their pain estimated as more severe (mean difference = 0.2), less exaggerated (mean difference = -0.1), more minimised (mean difference = 0.3), more likely to be caused by a mental health problem (mean difference = 0.4), and less likely to be caused by a physical health problem (mean difference = 0.2).

Table 5. Means (standard errors), *F* ratios, and *p* values, for the effect of ethnicity on pain judgments

	Asian patients	White patients	<i>F</i> (1, 105)	<i>p</i>
Questions				
"How severe do you think [the patient's] pain is?" <i>Scale from 0 (no pain) to 10 (worst possible pain)</i>	7.8 (0.1)	8.0 (0.2)	.693	.407
"How much do you think [the patient] is exaggerating her pain?" <i>Scale from 0 (no exaggeration) to 10 (strong exaggeration)</i>	2.5 (0.2)	2.6 (0.3)	.307	.581
"How much do you think [the patient] is minimising her pain?" <i>Scale from 0 (no minimisation) to 10 (strong minimisation)</i>	2.3 (0.2)	2.6 (0.2)	1.066	.304
"How likely is it that [the patient's] pain is caused by a mental health problem?" <i>Scale from 0 (very unlikely) to 10 (very likely)</i>	4.8 (0.2)	5.2 (0.2)	1.341	.249
"How likely is it that [the patient's] pain is caused by a physical health problem?" <i>Scale from 0 (very unlikely) to 10 (very likely)</i>	7.3 (0.2)	7.1 (0.2)	.543	.463

Note: values in bold denote significance ($p < .05$)

4.5 Impact of interactions between variables on pain judgments

Research Question 4: Do the variables of medical information (medically unexplained pain with no comorbidity, medically explained pain with no comorbidity, explained/unexplained pain with a comorbid MUS condition) and ethnicity interact to affect CBT therapists' judgments of pain?

There was no significant effect from the interaction between medical information and ethnicity on CBT therapists' judgments of pain (Table 6).

Table 6. Interactions between medical information and ethnicity on pain estimations

	Medical Information x Ethnicity F (2, 104)	<i>p</i>
Estimations of pain severity	.969	.383
Estimations of pain exaggeration	.500	.608
Estimations of pain minimisation	1.132	.362
Pain caused by mental health problem	.905	.406
Pain caused by physical health problem	2.958	.056

Note: values in bold denote significance ($p < .05$)

4.6 Impact of medical information and ethnicity on treatment decisions

Research Question 5: Are CBT therapists' treatment decisions affected by the variables of medical information and ethnicity?

A three-way loglinear analysis was used to determine whether there were any associations between the variables of ethnicity, medical information, and participants' treatment decisions. Section 3.5.4 provides more detailed information on the categories of these variables and the fit of the data to the assumptions for loglinear analysis.

The loglinear analysis produced a model that included all main effects and two, two-way associations between ethnicity and treatment priorities, and medical information and treatment priorities. The Pearson goodness-of-fit test indicated that the model was a good fit to the observed data, $\chi^2(6) = 0.588$, $p = .997$.

Total cell frequencies for each variable are shown in Table 7, and cell frequencies for all possible interactions of variables are shown in Table 8. Overall,

participants did not prioritise CBT for depression over specialist referral or specific psychological treatment protocols for pain (*hypothesis 5a*). Rather, most participants (72.6%) prioritised referrals to specialist services or psychological treatment protocols for pain.

Table 7. Total cell frequencies and percentages (out of the overall responses in each category) of participants' treatment decisions by the variables of ethnicity and medical information

Variable / Combination	Treatment Decision	Frequency	%
Overall	CBT for depression	88	27.4
	Referral to specialist for pain	124	38.6
	Psychological treatment protocol for pain	109	34.0
Ethnicity = white	CBT for depression	50	36.2
	Referral to specialist for pain	48	34.9
	Psychological treatment protocol for pain	40	28.9
Ethnicity = Asian	CBT for depression	38	20.8
	Referral to specialist for pain	76	41.5
	Psychological treatment protocol for pain	69	37.7
Medical information = medically unexplained pain only	CBT for depression	36	33.6
	Referral to specialist for pain	37	34.6
	Psychological treatment protocol for pain	34	31.8
Medical information = medically explained pain only	CBT for depression	18	16.8
	Referral to specialist for pain	48	44.6
	Psychological treatment protocol for pain	41	38.3
Medical information = comorbid CFS with explained/unexplained pain	CBT for depression	34	31.8
	Referral to specialist for pain	39	36.4
	Psychological treatment protocol for pain	34	31.8

Table 8. Cell frequencies and percentages (of overall responses) of participants' treatment decisions by the variables of ethnicity and medical information, as well as interactions of these variables

Variable / Combination	Treatment Decision	Frequency	%
[ethnicity = white] x [medical Information = medically unexplained pain only]	CBT for depression	21	6.5
	Referral to specialist for pain	13	4.0
	Psychological treatment protocol for pain	12	3.7
[ethnicity = white] x [medical information = medically explained pain only]	CBT for depression	10	3.1
	Referral to specialist for pain	20	6.2
	Psychological treatment protocol for pain	16	5.0
[ethnicity = white] x [medical information = comorbid CFS with explained/unexplained pain]	CBT for depression	19	5.9
	Referral to specialist for pain	15	4.7
	Psychological treatment protocol for pain	12	3.7
[ethnicity = Asian] x [medical Information = medically unexplained pain only]	CBT for depression	15	4.7
	Referral to specialist for pain	24	7.5
	Psychological treatment protocol for pain	22	6.9
[ethnicity = Asian] x [medical Information = medically explained pain only]	CBT for depression	8	2.5
	Referral to specialist for pain	28	8.7
	Psychological treatment protocol for pain	25	7.8
[ethnicity = Asian] x [medical information = comorbid CFS with explained/unexplained pain]	CBT for depression	15	4.7
	Referral to specialist for pain	24	7.5
	Psychological treatment protocol for pain	22	6.9

Although most participants preferred specialist referrals or psychological treatment protocols for pain, there were significant associations between ethnicity and treatment decisions (*hypothesis 5c*), as well as between medical information and treatment decisions (*hypotheses 5a and 5b*). Table 9 shows the partial likelihood ratios χ^2 (i.e. associations), degrees of freedom, and *p* values for the interactions between these variables. Table 10 shows the parameter estimates, Z scores and *p* values for the specific interactions that were the most predictive of cell frequencies.

In contrast with the hypothesis (5c), participants preferred CBT for depression significantly more for white patients than for Asian patients ($\lambda = .734$, $p = .002$) (Table 10). 36.2% of participants' prioritised treatment for depression for white patients, as opposed to 20.8% of participants who prioritised treatment for depression for Asian patients (Table 7).

In line with the hypotheses (5a and 5b), CBT for depression was the least preferred treatment option for patients with medically explained pain only ($\lambda = -.844$, $p = .020$) (Table 10). This means that treatment for depression was prioritised by more participants for patients with medically unexplained pain only and explained/unexplained pain accompanied by comorbid CFS (33.6% and 31.8% of participants respectively), than it was for patients with medically explained pain only (16.8% of participants).

Table 9. Partial associations, degrees of freedom, and p values for the interactions between the variables of ethnicity, medical information and treatment decisions

Variables	Partial Association χ^2	Degrees of Freedom	p
Interaction between ethnicity and treatment decisions	9.782	2	.008
Interaction between medical information and treatment decisions	9.995	4	.041

Note: values in bold denote significance ($p < .05$)

Table 10. Parameter estimates, Z scores and p values for the hierarchical model: interaction between ethnicity and treatment decisions, and interaction between medical information and decisions

Parameter	Estimate (standard error)	Z	p
Interaction: [ethnicity = white] x [treatment priority = CBT for depression]	.734 (.283)	3.056	.002
Interaction: [medical information = medically explained pain only] x [treatment priority = CBT for depression]	-.844 (.363)	-2.327	.020

Note. Z = Estimate (λ) / Standard Error; values in bold denote significance ($p < .05$)

4.7 Impact of training on treatment decisions

Research Question 6: Are CBT therapists' treatment decisions affected by the level of training that they have received in chronic pain, long-term conditions, or medically unexplained symptoms?

A chi-square test for association was conducted to determine whether there were associations between the two categorical variables of training (i.e. level of

participants' training in medically unexplained symptoms, chronic pain, or long-term conditions) and treatment decisions. Section 3.5.5 provides more detailed information on the categories of these variables and the fit of the data to the assumptions for the chi-square test.

10% of participants (N = 14) stated that they had no specialist training in treating MUS, chronic pain or long-term conditions, and 8% (N = 9) responded to indicate that they were had no knowledge of specific treatment protocols for pain or MUS. The remaining participants (N = 93) reported that they had received some training in treating MUS, chronic pain or long-term conditions, but half of these (N = 46) reported they had only received 1 day or less of training.

Cell frequencies for each variable are shown in Table 11.

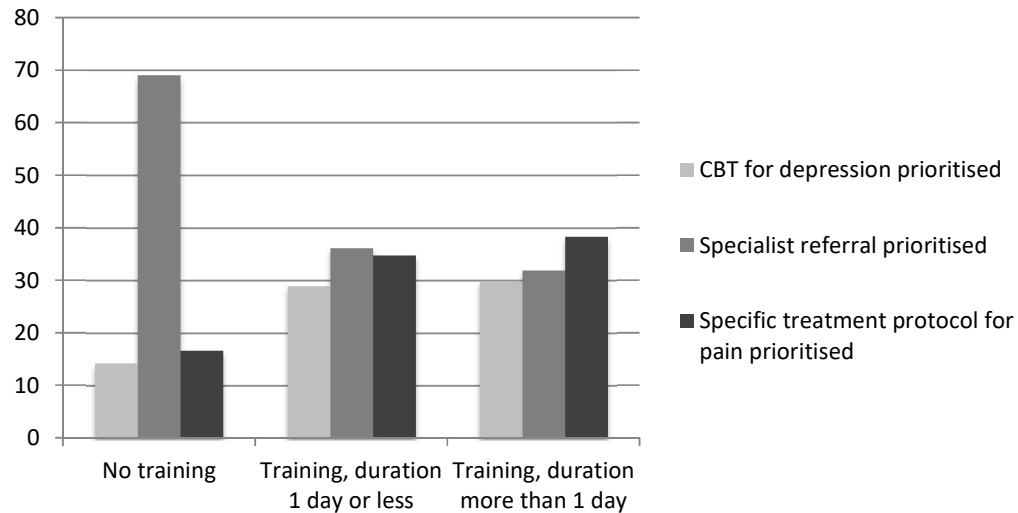
Table 11. Cell frequencies and percentages of participants' treatment decisions by the variable of training

Variable / Combination	Treatment Decision	Frequency	%
Overall	CBT for depression	88	27.4
	Referral to specialist for pain	124	38.6
	Psychological treatment protocol for pain	109	34.0
Training = no training	CBT for depression	6	14.3
	Referral to specialist for pain	29	69.0
	Psychological treatment protocol for pain	7	16.7
Training = training, duration less than 1 day	CBT for depression	40	29.0
	Referral to specialist for pain	50	36.2
	Psychological treatment protocol for pain	48	34.8
Training = training, duration more than 1 day	CBT for depression	42	29.8
	Referral to specialist for pain	45	31.9
	Psychological treatment protocol for pain	54	38.3

There was a statistically significant association between training and treatment preferences, $\chi^2(4) = 19.473$, $p = .001$. There was also a moderately strong association between participants' level of training (i.e. no training, training of duration less than one day, and training of duration more than one day) and their treatment preferences, $\phi = 0.174$, $p = .001$. Participants with no training, rather than preferring CBT for depression as hypothesised (*hypothesis 6a*), actually had a

strong preference for referring patients on to specialist services for pain (Figure 5). As the duration of training increased, so also did participants' preference for the use of CBT treatment protocols for pain.

Figure 4. Percentages of participants in each training category who preferred CBT for depression, specialist referral, or specific treatment protocols for pain



5. Discussion

This study investigated the effects of three variables on CBT therapists' judgments of pain and treatment decisions for patients with chronic pain. The first variable of interest in this study was the medical information given about a patient: whether their pain was presented as medically explained or unexplained, and whether their pain (explained or unexplained) was accompanied by a comorbid medically unexplained condition (CFS) or not. The second variable was the patient's ethnicity (white or Asian). Finally, the third variable was participants' levels of training in medically unexplained symptoms, long-term conditions, or chronic pain.

5.1 *The impact of a lack of medical explanation on CBT therapists' judgments of pain and treatment decisions*

The presence or absence of a medical explanation for pain was one of the main variables of interest in this study, and three of the four hypotheses related to

this variable (*hypotheses 1a, 1b, 5a*) were supported. Estimates of pain severity were overall high. However, patients with pain that was presented with a common medical explanation were consistently estimated to be in more severe pain than patients whose pain was presented as medically unexplained. Although this difference was associated with a medium effect size, the actual difference was small, at about half a point on a 0 – 10 scale. Thus, this was a small, but significant result.

Although estimates were low overall, patients with medically unexplained pain were also judged to be significantly more likely to be exaggerating their pain. This difference was slightly bigger than for pain severity estimates, at nearly three quarters of a point on a 0 – 10 scale, but it was still a small difference.

As hypothesised, CBT therapists were also more likely to prefer treatment for depression for patients whose pain was presented as medically unexplained. 33.6% of participants preferred treatment for depression for patients with medically unexplained pain, as opposed to 16.8% of participants who preferred CBT for depression for patients with pain presented with a common medical explanation.

These findings are in line with previous studies that have found that healthcare professionals frequently underestimate the severity of pain when it lacks a medical explanation (de Ruddere et al., 2014; de Ruddere, Goubert, Stevens, Williams & Crombez, 2013; de Ruddere, Goubert, Vervoort, Prkachin & Crombez, 2012; Tait & Chibnall, 1994). As previously highlighted, the genuine experience of chronic pain is not dependent on observable evidence of tissue damage or physical pathology. As a result, there is no scientific basis for even a small difference in pain judgments and resulting treatment decisions, based on the lack of a medical explanation for pain.

Although participants in general prioritised specific treatment protocols or specialist referrals for patients with pain, in light of the above, it is disconcerting that they preferred CBT for depression significantly more when pain was presented without a common medical explanation. One possible explanation is that

participants lacked knowledge of the credible causal mechanisms for chronic pain, or were influenced by outdated psychosomatic theories of pain, and this possibility will be discussed further in section 5.4. Alternatively, they could have been influenced by beliefs related to the authenticity of symptoms that are deemed to be medically unexplained, and this possibility will be explored more in section 5.2.

5.1.1 Pain minimisation

All hypotheses related to estimates of pain minimisation (*hypotheses 1c, 2c and 3c*) were unsupported by this study. As previously highlighted, and in contrast with popular stereotypes, patients with chronic pain frequently tend to hide or minimise their pain. As a result, it is a clinical problem that is often overlooked. This is consistent with the findings of this study, in which estimates of pain minimisation were very low and no significant differences were found between groups. This indicates that many of the CBT therapists who participated in this study probably lacked more in-depth knowledge of chronic pain and how it presents clinically.

5.2 The impact of a comorbid medically unexplained condition on CBT therapists' judgments of pain and treatment decisions

Comorbidity with a condition that is commonly described as medically unexplained, CFS, was also a primary variable of interest in this study. Again, four of the five hypotheses related to this variable (*hypotheses 2a, 2b, 2d, 5b*) were supported. Patients who were reported to have CFS and pain, regardless of whether or not their pain was presented as explained or unexplained, were consistently judged to be in less pain than patients with medically explained pain and no comorbid CFS. Patients with CFS were also judged to be significantly more likely to be exaggerating their pain. As with the previous variable, the actual difference in these ratings were fairly small, at about half to three-quarters of a point on a 0 to 10 scale.

In addition, patients with CFS were significantly more likely to have their pain, whether it was associated with a medical explanation or not, judged to be caused by

a mental health problem. This result was associated with a large effect size, and the actual difference was also large, at just over 2 points on a 0 to 10 scale. The mean rating for pain associated with comorbid CFS being caused by a mental health problem was nearly 6/10 (meaning fairly likely), whereas the mean rating for medically explained pain only was about 3.5/10 (meaning fairly unlikely). This was the largest difference found in this study.

As would be expected from these judgments, CBT therapists were also more likely to prefer CBT for depression for patients with CFS, regardless of whether their pain was explained or unexplained. This difference was even slightly more than for patients with medically unexplained pain only, with 33.6% of participants preferring treatment for depression for patients with comorbid CFS, as opposed to 16.8% of participants who preferred treatment for depression for patients with explained pain without comorbid CFS.

The potential implications of these findings for patients with CFS (and possibly other conditions currently described as medically unexplained) are substantial. These results show that the same patient referred for chronic pain could potentially have a very different treatment experience and working diagnosis (i.e. depression or difficulty adjusting to a physical health condition), not based on information about their pain or mood, but on whether or not the CBT therapist is made aware of their CFS diagnosis and holds certain biases about the mechanisms of chronic pain and medically unexplained symptoms. This result is troubling on a number of levels.

There is some overlapping symptomatology between depression and CFS, the primary symptom being fatigue/lack of energy, but also disturbed sleep, difficulties concentrating and making decisions (“brain fog”), and low mood (American Psychiatric Association, 2014; World Health Organization, 1992). However, CFS is not in the diagnostic criteria for depression, and at most it should be a part of a formulation rather than a critical factor in decisions regarding a working diagnosis or appropriate treatment options. In actuality, people with CFS are probably at risk of

overdiagnosis of depression because of the overlapping symptoms, particularly when their mood is impacted by their inability to engage in activities they enjoy due to severe and persistent fatigue. In addition, despite often being described as medically unexplained, CFS is a condition that has been found to be associated with adrenal, autoimmune, and psychosocial factors (Hyong et al., 2006). Thus, diagnosing and treating a patient for depression rather than chronic pain, simply based on their additional diagnosis of CFS, would be a misguided and potentially harmful decision.

These findings are in line with previous research that has highlighted healthcare providers' beliefs that patients with medically unexplained symptoms tend to be manipulative and exaggerate their symptoms, or that medically unexplained symptoms are the result of mental health problems (Shattock et al., 2013). Likewise, these results provide some evidence for patients' perceived stigma associated with a CFS. People with CFS and other conditions described as medically unexplained have reported that they feel disbelieved by health professionals, and that their symptoms are judged to be illegitimate, fabricated, or caused by a mental health problem (Sim & Madden, 2008; Stone et al., 2002). This study corroborates those fears.

5.3 The impact of ethnicity on CBT therapists' judgments of pain and treatment decisions, and the interaction between the variables of ethnicity and medical information

This study also aimed to investigate the impact of ethnicity on CBT therapists' judgments of pain and treatment decisions. However, all five hypotheses related to this variable were unsupported (*hypotheses 3a, 3b, 3c, 3d, 5c*). Although pain judgments for white and Asian patients showed differences that were in line with the hypotheses, these were not significant. There was also no significant interaction found between the variables of ethnicity and medical information.

The one significant result that was found for the variable of ethnicity was actually in direct contrast with what was hypothesised (5c). This was the finding that treatment for depression was preferred by significantly more participants for white patients rather than Asian patients. This was a significant difference, with 36.2% of participants' prioritising treatment for depression for white patients, as opposed to 20.8% of participants prioritising treatment for depression for Asian patients.

These findings are at odds with a longstanding body of research that has found significant effects on pain judgments and treatment decisions for patients from ethnic minority backgrounds. Previous studies have consistently shown that patients from ethnic minority backgrounds tend to have their pain underestimated, and this has a negative impact on their treatment and the management of their symptoms (Anderson et al., 2009; Balsa & McGuire, 2003; Green et al., 2009; Hausmann et al., 2013, Tait & Chibnall, 2014).

As a result, the absence of significant differences in pain judgments between ethnic groups is difficult to interpret. It could be that, with time, the unconscious biases demonstrated by research are having less of an influence over healthcare providers' judgments of pain in general, or that CBT therapists in the ethnically diverse area of London are less susceptible to these biases. Alternatively, it may be something about the computer-generated faces or design used in this study (i.e. participants being allocated to see all white or all Asian patients) that either allowed participants to guess the purpose of the study, or did not emphasise the ethnicity of the patient enough to trigger unconscious racial biases. Another study that used vignettes to test racial disparities in pain judgments also failed to find typical effects, and hypothesised that this type of stimulus does not capture essential aspects of the clinical experience, such as poor doctor-patient rapport and stigmatising behaviours (Burgess et al., 2008). However, if any of these possible explanations were wholly accurate, no variables would be expected to show significant differences between

ethnic groups, when in fact one significant difference in treatment decisions was found.

The finding that CBT for depression (the treatment option that is considered the least appropriate for all patients in this study) was significantly more preferred for white patients is puzzling. Although this finding could mean that Asian patients referred with chronic pain are more likely to receive an appropriate treatment for chronic pain, it may also indicate that it would be difficult for Asian people to access psychological treatments for mental health problems in primary care.

There are a number of possible explanations for this difference in treatment preferences, all of which are open to speculation. For example, it may be that participants believed that Asian patients would not be amenable to psychological therapy for a mental health problem. This belief would be in line with some literature that suggests it can be difficult to engage Asian patients in psychological treatments, although there are a number of potential reasons for this, and the difficulty is likely to be as much on the part of practitioners as it is for patients. Alternatively, it could be due to an unconscious bias against working with Asian patients, resulting in a higher preference for onward referral. These possible explanations are equally likely, as 41.5% of participants preferred onward referrals to specialist services for pain for Asian patients (as opposed to 34.9% for white patients), and 37.7% of participants preferred a psychological treatment protocol for pain for Asian patients (as opposed to 28.9% for white patients).

On the other hand, it is encouraging that CBT therapists did not appear to have a bias against referring Asian patients to specialist services for difficulties related to CFS or chronic pain. It has often been reported that ethnic minorities are underrepresented in specialist services for pain (Green et al., 2003). These results could indicate that CBT therapists are better at recognising people from ethnic minority backgrounds with difficulties that would benefit from referral to specialist services for chronic pain.

5.4 The impact of CBT therapists' levels of training on treatment decisions

Finally, this study investigated the impact of training in chronic pain, MUS, or long-term conditions on CBT therapists' treatment decisions. Overall, CBT therapists showed a strong preference across groups for treatment for pain (e.g. referrals to specialist services or psychological treatment protocols for pain) over treatment for depression. A statistically significant association was also found between participants' level of training and treatment decisions. However, this was not in the way expected. In contrast with the hypothesis (6a) that participants with no training would prefer CBT for depression, they actually showed a strong preference for referring patients on to specialist services for pain. It was also found that CBT therapists who reported having received more training also showed a stronger preference for the use of specific treatment protocols for pain.

In addition, 87% of participants reported that they had received at least some training in MUS, chronic pain or long-term conditions, and half of these said that they had received more than 1 day of training. Only 13% of participants stated that they had received no training, and just 8% responded to indicate that they had no knowledge of specific treatment protocols for pain.

These results are very encouraging, and are in contrast with some preliminary research that indicated that few treatment manuals are available for working with medically unexplained symptoms and chronic pain, and that many primary care CBT therapists feel less competent in treating these conditions (Lewis, 2013). However, these results are also inconsistent with the troubling finding (discussed in sections 5.1 and 5.2) that CBT for depression was preferred for patients with medically unexplained pain and comorbid CFS. Together, these findings suggest that, while the overall picture of primary care CBT therapists' training and treatment decisions with regards to pain is promising, there are likely to be persistent unconscious biases that impact on how CBT therapists conceptualise and treat pain for patients

from ethnic minority backgrounds, as well as patients with medically unexplained symptoms.

5.5 Study limitations

This study has a number of limitations that may have had an impact on the accuracy of the results. Firstly, the computer-generated images of patient faces may not have been a sufficient prompt to trigger biases related to the patient's ethnicity. This insufficiency could have been related to either the image itself or to the prominence of the image in relation to the written vignette. For example, participants in this study could have spent the majority of their time reading the written vignette, only briefly glancing at the still image of the patient's face. There is no way to know in this study whether this could be the case. However, this online study could have been configured in a way that would have required participants to view the patient's face for a specified time period. In addition, the ethnicity of the computer-generated face could have been empirically validated, as well as emphasised in the written vignette.

Alternatively, the use of videos of patients or actors portraying patients in pain (rather than a still image of a patient's face) may have increased the ecological validity of the study, and potentially could have resulted in participants spending more time on visually viewing the patient before moving on to the written information. However, the use of these alternative stimuli would have also introduced many other confounding factors, and would not have allowed for the high level of control over facial expressions that was a feature of this study.

The data that was gathered in this study about participants' level of training in MUS, chronic pain or long-term conditions was non-specific and brief, and more detailed and specific information on this might have aided in the interpretation of results. No questions were asked about the content of the training, and the assessment of the length of training gave limited information (i.e. whether the training had a duration of more or less than one day). As a result, it is possible that

some of this training was for health conditions that are not primarily associated with pain, such as chronic obstructive pulmonary disease or diabetes. Equally, it is possible that most of the training received was of insufficient quality or length to adequately educate participants about the causal mechanisms and appropriate treatment of chronic pain. As a result, more detailed information on the content and length of training would have been useful.

Likewise, the data analysed about treatment decisions gave a broad picture of treatment preferences rather than a specific breakdown, and this study did not investigate the rationale that CBT therapists may have had for their treatment decisions. More specific information on treatment decisions could have been obtained by asking CBT therapists to indicate why they preferred some treatment options to others. For example, with regards to referring to specialist services, participants could have been given the option to indicate that a particular service was unavailable in their area, or that it had stringent referral criteria that they believed would not be met. Alternatively, when indicating a preference for a particular treatment model to use with the patient, participants could have been given the option to cite a reason for that preference (for example, believing that the patient would not engage with or benefit from a specific treatment).

Finally, it is worth considering whether the methods of recruitment had an impact on the results of this study. As previously detailed, the original intention for this study was to recruit participants directly from nine primary care NHS services. However, recruitment was much lower than anticipated from conversations with service managers, and was therefore widened to social media and emails from CBT education providers. It is possible that recruiting through social media and email lists, rather than directly through participating services, means that more of the CBT therapists who chose to participate in this study did so because they were more interested (and therefore possibly better educated) in treating patients with chronic pain. This could have had an impact on the results of this study, in which it was

hypothesised that less training and knowledge about medically unexplained symptoms and chronic pain could lead to unhelpful biases in pain judgments.

5.6 Clinical and research implications

5.6.1 Clinical implications

If the results of this study are taken to mean that CBT therapists are influenced by biases and beliefs regarding patients with chronic pain and medically unexplained symptoms, then there are a number of implications for clinical practice. First and foremost, these results suggest that patients may have very different experiences of psychological therapy (in terms of recommended treatments and the stance of the therapist on their pain) based the presence or absence of a medical explanation for their symptoms. Decisions based on these factors have no scientific basis, and confirm the fears of many people who experience medically unexplained symptoms.

Biased judgments for patients with chronic pain may lead to inappropriate treatments being offered, which in turn could lead to higher levels of patient dropout or poor response to interventions. At the very least, this would prevent patients with chronic pain from accessing an evidence-based treatment that could help them to better cope with their symptoms and reduce levels of disability and use of healthcare resources. At the very worst, this would lead to increased levels of distress in patients with chronic pain, which in turn could increase their levels of functional impairment and health resource use. These biases are also potentially self-confirming, in that higher levels of distress and dropout could perpetuate the view that people with medically unexplained symptoms primarily have a mental health difficulty and are difficult to engage and treat.

Given the potential implications for patients, it is exceedingly important to address the biases that CBT therapists may hold about people with 'medically unexplained' symptoms or conditions as well as those from Asian ethnic backgrounds. Particularly if these biases are explicit, they may respond to better

education and training. Indeed, this study as well as previous research (Lewis, 2011) indicates that CBT therapists in the UK could benefit from more training in medically unexplained symptoms and chronic pain. This training would need to be of sufficient quality and breadth in order to give CBT therapists adequate scientific knowledge about the mechanisms behind chronic pain and medically unexplained symptoms.

However, previous research has found that education and training alone may not be enough to address implicit biases (Drwecki, Moore, Ward & Prkachin, 2011). A review of implicit bias in healthcare providers found a number of studies that used various strategies to successfully reduce bias (Chapman et al., 2013). Some of these strategies involved increasing clinicians' awareness of their susceptibility to bias, as well as the provision of feedback regarding their potential biases in treatment decisions. The review also suggested that there is some evidence that, even without increased awareness, implicit bias can be reduced when clinicians have more information about the patient or are asked to focus on the individual qualities of the patient rather than the social and diagnostic categories that they belong to. Thus, CBT therapists may benefit from hearing people with chronic pain and medically unexplained symptoms describe their experiences and the impact of these on their daily lives.

More broadly, it is likely that a wider shift in psychological thinking away from psychosomatic theories will be necessary, particularly in relation to chronic pain. Given the long history of these theories, the established complex interactions between psychosocial factors (mind) and 'physical' mechanisms of disease (body), and the surprising number of conditions and mechanisms that science continues to fail to explain, changing psychological perspectives to a more nuanced and scientific view of 'medically unexplained' conditions is likely to be a lengthy and difficult process that is frequently fraught with uncertainty. Nevertheless, this is an exceedingly important task. The more that CBT therapists are exposed to what is

known and not known about medically unexplained symptoms and chronic pain, the more likely they will be able to effectively intervene and support patients with these conditions.

Healthcare policies and guidelines could play a part in bringing about this shift in thinking and reducing biases, particularly in light of their potential role in generating these biases that was highlighted in the introduction to this paper. Guidance documents should reflect our best evidence-based understandings of medically unexplained symptoms and chronic pain. They should also be careful about not inferring causal mechanisms from correlations between psychosocial stress and comorbid conditions in the diagnosis of medically unexplained symptoms.

5.6.1 Research implications

This study indicates that, as is found in medical professionals, CBT therapists may hold biased beliefs about people with medically unexplained symptoms and chronic pain. More research on these potential biases would be prudent, particularly in light of the recent government initiatives that push for more people with these difficulties to be referred for psychological therapy.

In addition, this study provides evidence for stigma associated with diagnoses that are commonly described as medically unexplained (such as Chronic Fatigue Syndrome). Patients and patient advocacy groups have highlighted their experiences of this stigma, but there has been little research on this. This stigma could have an impact on the way that patients are viewed and treated by healthcare services and professionals, as well as by the general public. As a result, there is a need for further research in this area.

6. Conclusion

This study contributes to a wide body of research on the factors that trigger biases in healthcare providers' judgments of pain and treatment decisions for patients of different ethnicities, and with chronic pain and 'medically unexplained'

symptoms. These findings provide evidence that CBT therapists judge pain to be less serious and more exaggerated when patients experience pain that is presented without a medical explanation, or is accompanied by a comorbid 'medically unexplained' condition. These factors were also found to have an impact on treatment decisions, with CBT therapists showing a stronger preference for treatment for depression when patients presented with medically unexplained symptoms. The ethnicity of the patient did not have a consistent effect in this study, but it was found to have an influence on CBT therapists' treatment decisions, with a higher preference for treatment for depression for white patients over Asian patients. The potential implications for the treatment of patients with these factors are substantial, and many recommendations are made for the training and education of CBT providers in order to reduce biases.

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Part 3: Critical Appraisal

In this critical appraisal, I will reflect on my experiences of conducting and reporting the systematic literature review and meta-analysis, as well as the empirical study. I will explain how my perspective on ‘medically unexplained symptoms’ influenced the way I began this process, as well as how my views changed over time. I will also discuss the theoretical, semantic and practical challenges I faced, my attempts to overcome these difficulties, and my thoughts on how they could have been managed differently.

1. The start of the process

My interest in chronic pain and ‘medically unexplained symptoms’ was fostered through personal experiences, as well as through three years of working in primary care psychology services (IAPT) prior to starting the DClinPsy. Throughout my time working in IAPT services, I assessed and attempted to offer interventions for many people who were ostensibly referred for low mood or anxiety, but presented with ‘unexplained’ physical symptoms or conditions as their primary difficulty. I met people who described experiencing chronic fatigue, chronic pain, gastrointestinal symptoms, tinnitus, and headaches, and heard about the enormous impact these symptoms could have on a person’s ability to live their life normally.

These patients with ‘medically unexplained’ symptoms often described feeling unable to engage in activities such as work, activities with family and friends, exercise, or even getting out of bed in the morning. They also frequently expressed feelings of frustration with healthcare professionals who seemed dismissive, and were so often unable to offer any explanation or treatment for their difficulties. And, invariably, they would stress that these symptoms had affected their mental health, and not the other way around.

Hearing these stories of suffering from patients, and armed with – from my perspective – my minimal low-intensity IAPT training, my task was to offer an intervention that would improve their functioning and emotional wellbeing. In the resulting interactions, I would often feel two conflicting emotions. On the one hand, I

wholly believed in the experiences described to me and empathised with the enormous impact these symptoms had on patients' lives. Nevertheless, as I attempted to implement any of the interventions I was trained to offer – increasing activity (i.e. behavioural activation), problem-solving, challenging unhelpful beliefs (i.e. cognitive restructuring) – I frequently experienced greater than usual difficulties, and the overall rate of 'recovery' for these patients was disappointingly low. As a result, I found myself in the curious position of feeling a great deal of empathy for these patients, but also experiencing a degree of trepidation and hopelessness when they ended up on my caseload.

As I gained further knowledge and experience in implementing psychological therapies through the DClinPsy training (including a Health Psychology placement), both my interest in chronic pain and medically unexplained symptoms, and my empathy for the people who struggle with these experiences grew. I realised that my lack of knowledge and experience in offering interventions for chronic pain and medically unexplained symptoms was probably the primary reason for my previous difficulties with these patients, and I became interested in using this experience to improve interventions. It was from this position, then, that I embarked on my literature review and empirical research.

Throughout the process of reviewing the literature on medically unexplained symptoms and chronic pain (in preparation for the empirical study as well as the meta-analysis), I became increasingly doubtful of the usefulness of 'medically unexplained symptoms' as a diagnostic category and label, as well as increasingly incredulous of the number of conditions that were described as 'medically unexplained', but actually had evidence-based causal mechanisms that were widely described in the literature. In addition, I became increasingly concerned about the role my profession had potentially played in perpetuating these misconceptions, and the impact this could have on patients. These issues (and my reasoning) are

covered extensively in both the literature review and meta-analysis, as well as in the report of my empirical research.

With this renewed sense of empathy and desire to advocate for patients with symptoms deemed to be ‘medically unexplained’, I decided to focus my literature review and empirical research on the effectiveness of psychological interventions and the judgments and treatment decisions of the people who implement them. And it was with this theoretical stance and strength of feeling that I approached the proposal, design and protocol for my empirical research.

Looking back on this process and the research protocol I produced, it is clear to me that I largely disregarded my own experiences, as well as the research on the struggles and dilemmas that healthcare professionals face when they are attempting to diagnose, effectively intervene, and communicate with people who experience symptoms that seem to be medically unexplained. When I read descriptions such as “heartsink patients” in the literature (Mathers, Jones, & Hannay, 1995), I interpreted that mostly as a failure of empathy on the part of healthcare professionals, rather than remembering my own struggles with that same feeling.

This failure to fully acknowledge the difficulties on both sides of the doctor-patient relationship was evident in the rationale for my research presented in my proposal and protocol. As I went through the process of obtaining ethical approval through NHS Trusts and individual services, I received feedback questioning whether I was biased against CBT therapists. These comments led me to reevaluate the strength of my stance, and to think more carefully about the complexity and difficulties that both patients and professionals face when attempting to manage chronic pain and ‘medically unexplained’ symptoms.

3. Negotiating a social minefield

Attempting to be more considered and diligent in my research, reasoning, and writing within the complex area of chronic pain and medically unexplained symptoms was a recurring theme for the remainder of my DClinPsy work. Often this

was an exceedingly difficult aim, as even when my reasoning was clear, it was often difficult to communicate my thinking in a way that would be of service to both professionals and patients and not risk misrepresenting, neglecting or offending either side.

I am not the first researcher to struggle with this issue, particularly in the controversial areas of chronic pain and medically unexplained symptoms. In my review of the literature, I read many reports of studies that neglected to fairly represent both professionals and patients either in the way the authors wrote about an issue or, more troubling, in the way that they interpreted and analysed their data. A number of these studies also attracted criticism from patients and patient advocates as well as from professionals.

This process of reviewing the literature increasingly reinforced in my mind the importance of having a clearly considered and communicated (and, as much as possible, evidence-based) rationale for my theoretical stance, research decisions, and analyses. Conducting research in a controversial area that has conflicting theoretical perspectives and real-world implications, particularly as someone who is new to the field, proved to be quite complicated when I was questioning ideas on which professional careers had been built and could potentially have a very real impact on the lives of patients. Thus, it felt imperative to consider all sides in an unbiased and fair way.

At the same time, I recognised that the primary goal of this research was to, as far as is possible, conduct unbiased research and analyses that would have the potential to provide useful insights to professionals and benefit patients. Thus, if a particular finding or analysis led to a strong conclusion, it would not benefit either side to dilute the message in order to reduce the risk of offence. Thus began a constant struggle in which I frequently became bogged down in making a clear argument, whilst ensuring that I fairly represented both sides.

4. Negotiating a semantic and theoretical minefield

In addition to my difficulties in ensuring that I communicated in a clear and fair way for both professionals and patients, I also struggled at a more fundamental level with the use of the term ‘medically unexplained symptoms’ (and any of the equivalent labels described in my review and empirical papers). My analysis of the literature and evidence-base for this term clearly led me to the conclusion that it was both an inaccurate and misleading, as well as clinically and empirically unhelpful diagnostic label.

The biggest problem I had with the label was its broad and imprecise use to describe innumerable symptoms and conditions that medicine and science had yet to explain, and in some cases (as with chronic pain) had an evidence-based explanation but continued to be described as ‘unexplained’ (Williams & Johnson, 2011). After examining the literature and evidence-base, I was not convinced that a patient with chronic pain experienced the same condition (or underlying causal mechanisms) as someone with tinnitus or chronic fatigue; nor was I certain that they would respond to the same interventions or components of interventions.

Thus, I found myself in the complicated position of conducting research on a diagnostic category that I did not have confidence in. This was particularly difficult when it came to writing the reports of my work, because it was important that I both clearly explained my theoretical stance as well as my rationale for using the diagnostic category in my research. This is certainly not a unique situation, and it is arguably most effective to work within a paradigm in order to raise questions about it and point out anomalies in the framework. However, it was nonetheless a difficult and time consuming process to ensure that I chose my words carefully and clearly communicated my arguments.

Negotiating this semantic and theoretical minefield was made further complicated by the need to communicate arguments about the mind (e.g. “mental” or psychological states) and body (e.g. “physical” or bodily states), without

suggested a dualistic position. The idea of mind-body dualism has been debated by philosophers since the time of Plato (and more recently by healthcare professionals and scientists) (Brown, 1988), and will not be detailed in full here. However, on a practical level, it was a challenge to balance the need to use terms like “mental” and “physical” to clearly communicate ideas, with the need to acknowledge that these are two interacting components of a whole human being (Duncan, 2000).

5. Remembering the destination

Being aware of, and attempting to manage these difficulties through careful thinking and writing was undoubtedly an important part of the process of conducting and reporting this research. However, there were times when I became nearly paralysed by these difficulties and struggled to think or write my way out of them. It was at these times, that it was helpful to remember why I had wanted to conduct this research in the first place.

The overriding purpose of this research was to benefit patients. This benefit could be achieved by providing useful insights to scientists and professionals (e.g. CBT therapists) that would then contribute to improvements in research and clinical practice for patients with ‘medically unexplained symptoms’ or chronic pain. Alternatively, patients could benefit from direct consumption of the research, which could provide them with information about their condition and the effectiveness of available treatments, as well as insights about the way their experiences are conceptualised by professionals. However, in either case, the interests of patients should always come first.

Remembering this purpose helped me to see my way through the semantic and theoretical minefield when I was feeling very stuck. And, although I am sure there are many improvements that could be made in the way that I have communicated my arguments, I am sure that always holding the patient in mind improved the work.

I would advise that future researchers, particularly in the complex field of 'medically unexplained symptoms', spend a large proportion of their time in the planning stage ensuring that they are clear on their theoretical stance (and its strength and weaknesses) and the purpose of their research. Once you know where you are going and why you are going there, it becomes much easier to negotiate the journey. Remembering the purpose of what you are doing also helps you to avoid pitfalls like offending or seeming biased against the professionals you are working with, or interpreting results in a way that is a disservice to patients. And, even more importantly, it makes it easier to follow through on drawing strong conclusions when these are justified – even if this means stepping on a mine that you hoped to avoid.

6. Reflections on practical challenges

Aside from the social, semantic and theoretical challenges throughout the process of this research, there were also practical challenges. One of these difficulties was in recruiting participants for the empirical research. The original plan for this study was to recruit CBT therapists directly from nine primary care psychological therapy services (IAPT services) in the NHS, and a great deal of time was spent gaining ethical approval and sponsorship through UCL, and then gaining additional ethical approval from the six different NHS Trusts that managed these services.

Not only did this process of gaining ethical approval introduce a significant delay in the research, but there was then a very low level of participation from staff in these services. The online study had been designed with busy CBT therapist in mind, and was anticipated to take a maximum of 15 minutes to complete (actual completion times averaged about 7 minutes). Additional efforts were also made to engage the therapists in the research, with many of the services being visited and reminded multiple times about the research. However, after over a month of recruitment, only a fraction of the numbers anticipated through discussions with service managers had participated, and recruitment had to be widened through the

use of social media and emails from CBT education providers. In the end, half of the participants came from this additional recruitment.

This change in the recruitment method was concerning, as it potentially resulted in a different demographic of participants. It had been decided to recruit directly through NHS services in order to gain the most accurate picture of how the typical CBT therapist working in a non-specialist IAPT service would respond. Recruiting through social media and emails from CBT education providers potentially meant that CBT therapists with a larger interest or higher levels of training in chronic pain or medically unexplained symptoms were more likely to be recruited. Equally, CBT therapists from pilot IAPT services focusing on long-term health conditions could also have been more likely to respond. These changes in participant demographics could have changed the results of the study, but there is no way of knowing if this is the case from the data collected.

IAPT services are a potentially rich source of data for psychological research, primarily because they see large numbers of patients with a variety of difficulties, and are accustomed to regularly collecting outcome data. However, there is also a strong focus on cost-efficiency, and CBT therapists in IAPT services frequently have large caseloads and very busy schedules. As a result, service managers are often mindful of the additional pressures that participation in research can place on staff and the knock-on effect this can have on overall service performance targets.

Possibly for these reasons, it was difficult to find service managers who would agree for their service to participate in this research, and it was also difficult to recruit the desired number of CBT therapists from the services that did agree to participate. Thus, with hindsight, I would have been much more conservative in my estimates of the number of CBT therapists that could be recruited from each service. In addition, I would only proceed with gaining the ethical approvals to

recruit directly from IAPT services if I was able to gain permission from enough services in order to meet the recruitment target.

On a wider level, it would be beneficial if more researchers would engage with IAPT services. In my contacts with service managers, a number of them seemed to be surprised by my proposal to recruit their staff for research, and many were also unaware of their Trust's protocols for conducting or participating in research. This indicates that, whilst they collect outcome data regularly, many IAPT services are not accustomed to participating in or conducting research. IAPT services are a potentially great resource for researchers, and it would be a shame for them not to be utilised.

Equally, IAPT services are often under increasing pressure from commissioners and governments to provide efficient and effective interventions for a wide variety of difficulties (Commissioning Support for London, 2010; Department of Health, 2011, 2014). As a result, they stand to benefit a great deal from research that contributes to the evidence-base for interventions and provides insights into what treatments (and what components of these treatments) work best for particular patients and difficulties.

7. Conclusion

Despite the challenges I have discussed here, I hope that those who are considering conducting research in chronic pain or medically unexplained symptoms (or even simply in IAPT services) are not discouraged from doing so. Engaging in the process of this research and learning to manage the many challenges has only increased my interest in this field. I hope that I will have more opportunities to contribute to the debate and evidence-base around medically unexplained symptoms in the future, and I hope that many others will join me.

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Appendices

Appendix 1: Example search strategy

(CENTRAL)□

1. somatization OR somatization OR somatoform or hysteri* OR polysymptom* OR multisomatoform OR somatizer*
2. (somatic NEAR symptom*)
3. MUS OR MUPS OR "medical* unexplained" or "unexplained medical**"
4. unexplained NEAR (symptom* or syndrome*)
5. "frequent attend**"
6. (multiple NEAR ("physical symptom**" or "symptom diagnos**"))
7. neurastheni*
8. function NEAR (disorder* OR symptom* OR syndrom* OR condition*)
9. "chronic pain" OR "idiopathic pain" OR "unexplained pain"
10. FMS OR fibromyalgia
11. CFS OR "chronic fatigue"
12. IBS OR "irritable bowel syndrome"
13. "temporomandibular joint" OR TMJ
14. (unexplained NEAR fatigue)
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. (CBT OR "cognitive behav* therap**" OR "cognitive therap**" OR "behav* therap**" OR "cognitive beh**" OR cognitive-beh**" OR cognitive NEAR (therapy OR treatment OR rehabilitation) OR behav* NEAR (therapy OR treatment OR rehabilitation)
17. 15 and 16
18. Limit: January 2005 to December 2015

Appendix 2: Ethical approval letter - UCL

UCL RESEARCH ETHICS COMMITTEE
ACADEMIC SERVICES



9 September 2015

Dr Amanda C de C Williams
Research Department of Clinical, Educational and Health Psychology,
UCL

Dear Dr Williams

Notification of Ethical Approval

Project ID: 2584/001: The impact of medical information, comorbidity, and ethnicity on CBT therapists' judgements of chronic pain

In my capacity as Chair of the UCL Research Ethics Committee (REC), I am pleased to confirm that I have approved your study for the duration of the project i.e. until June 2016.

Approval is subject to the following conditions:

1. You must seek Chair's approval for proposed amendments to the research for which this approval has been given. Ethical approval is specific to this project and must not be treated as applicable to research of a similar nature. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing the 'Amendment Approval Request Form' : <http://ethics.grad.ucl.ac.uk/responsibilities.php>
2. It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator [REDACTED] immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Vice-Chair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.

For non-serious adverse events the Chair or Vice-Chair of the Ethics Committee should again be notified via the Ethics Committee Administrator [REDACTED] within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Chair or Vice-Chair will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

On completion of the research you must submit a very brief report of your findings/concluding comments to the Committee, which includes in particular issues relating to the ethical implications of the research.

With best wishes for the research.

Yours sincerely

Professor John Foreman
Chair of the UCL Research Ethics Committee

Academic Services, 1-19 Torrington Place (9th Floor),
University College London

<http://ethics.grad.ucl.ac.uk/>

Appendix 3: Confirmation of UCL sponsorship for recruitment in NHS Trusts

NHS R&D Form

IRAS Version 5.2.0

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

Please note: The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr David Wilson on 20/01/2016 13:34.

Job Title/Post: UCL Sponsor representative
Organisation: UCL
Email: [REDACTED]

Appendix 4: Confirmation of NHS Trust Approval – BEH



www.noclor.nhs.uk

29/02/16

Mrs Brittni Jones
Research Department of Clinical, Education and Health Psychology (UCL)
Gower Street
London
WC1E 6BT

Dear Mrs Jones

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in the trust(s) identified below:

Study Title: CBT Therapists' Perceptions of Pain R&D reference: 172371 REC reference: N.A		
Name of the Trust	Name of current PI/LC	Date of permission issue(d)
Barnet Enfield and Haringey NHS Mental Health Trust	Dr Evi Aresti	29/02/16
If any information on this document is altered after the date of issue, this document will be deemed INVALID		

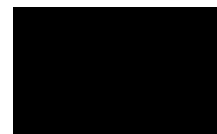
Specific Conditions of Permission (if applicable)
If any information on this document is altered after the date of issue, this document will be deemed INVALID

Yours Sincerely,



Pastipsen Joshi
Research Operations Manager

Appendix 5: Confirmation of NHS Trust Approval – CNWL



www.noclor.nhs.uk

29/02/16

Mrs Brittni Jones
Research Department of Clinical, Education and Health Psychology (UCL)
Gower Street
London
WC1E 6BT

Dear Mrs Jones

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in the trust(s) identified below:

Study Title: CBT Therapists' Perceptions of Pain R&D reference: 172371 REC reference: N.A		
Name of the Trust	Name of current P/IC	Date of permission issue(d)
Central and North West London NHS Foundation Trust	Dr Claire Pollard	29/02/16
If any information on this document is altered after the date of issue, this document will be deemed INVALID		

Specific Conditions of Permission (if applicable)

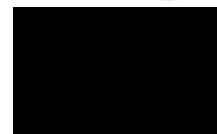
If any information on this document is altered after the date of issue, this document will be deemed INVALID

Yours Sincerely,



Poojaprasad Joshi
Research Operations Manager

Appendix 6: Confirmation of NHS Trust Approval – ELFT



www.noclor.nhs.uk

29/02/16

Mrs Brittni Jones
Research Department of Clinical, Education and Health Psychology (UCL)
Gower Street
London
WC1E 6BT

Dear Mrs Jones

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in the trust(s) identified below:

Study Title: CBT Therapists' Perceptions of Pain R&D reference: 172371 REC reference: N/A		
Name of the Trust	Name of current P/LC	Date of permission issue(d)
East London NHS Foundation Trust	Ms Debbie Davies and Ms Lorraine Davies-Smith	29/02/16
If any information on this document is altered after the date of issue, this document will be deemed INVALID		

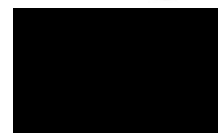
Specific Conditions of Permission (if applicable)
If any information on this document is altered after the date of issue, this document will be deemed INVALID

Yours Sincerely



Poojipoon Joshi
Research Operations Manager

Appendix 7: Confirmation of NHS Trust Approval –
The Whittington Health NHS Trust



www.noclor.nhs.uk

29/02/16

Mrs Brittni Jones
Research Department of Clinical, Education and Health Psychology (UCL)
Gower Street
London
WC1E 6BT

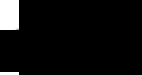
Dear Mrs Jones

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in the trust(s) identified below:

Study Title: CBT Therapists' Perceptions of Pain R&D reference: 172371 REC reference: N.A		
Name of the Trust	Name of current PI/LC	Date of permission issue(d)
The Whittington Health NHS Trust	Ms Kimberly Friedner	29/02/16
If any information on this document is altered after the date of issue, this document will be deemed INVALID		

Specific Conditions of Permission (if applicable)
If any information on this document is altered after the date of issue, this document will be deemed INVALID

Yours Sincerely,



Pushpen Joshi
Research Operations Manager

Appendix 8: Confirmation of NHS Trust Approval – NELFT



Research and Development Office
North East London NHS Foundation Trust,
1st Floor Maggie Lilley Suite,
Goodmayes Hospital,
Barley Lane,
Goodmayes,
Essex, IG3 8XJ

1st March 2016

Dear Brittni Jones,

RE: The impact of medical information, comorbidity, and ethnicity on CBT therapists' judgment of chronic pain.
R&D Ref: 2378

I am pleased to inform you that the above named study has been granted approval and indemnity by North East London NHS Foundation Trust. You must act in accordance with the North East London NHS Foundation Trust's policies and procedures which are available to you upon request, and the Research Governance Framework. Should any untoward events occur, it is **essential** that you contact your Trust supervisor and the Research and Development Office immediately. If patients or staff are involved in an incident, you should also contact the Governance and Assurance department, in Goodmayes Hospital, and complete the Incident and Reporting Form, namely the IR1 form.

You must inform the Research and Development Office if your project is amended and you need to re-submit it to the ethics committee or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records.

You are also required to inform the Research and Development Office of any changes to the research team membership, or any changes in the circumstances of investigators that may have an impact on their suitability to conduct research.

You must inform the Research and Development Office if your project is amended and you need to re-submit it to the ethics committee or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records.

You are also required to inform the Research and Development Office of any changes to the research team membership, or any changes in the circumstances of investigators that may have an impact on their suitability to conduct research.

Yours sincerely,

A black rectangular box redacting the signature of Fiona Horton.

Fiona Horton

Appendix 9: Confirmation of NHS Trust Approval – WLMHT

West London Mental Health NHS Trust

Mrs Britni Jones
Research Department of Clinical, Education
and Health Psychology
University College London
Gower Street
London WC1E 6BT

West Mental Health Trust R&D Office
Trust Headquarters
1st Floor, Wing B
1 Armstrong Way
Middlesex
UB2 4SD

31 March 2016

Dear Mrs Jones

Study Title: The impact of medical information, comorbidity, and ethnicity on CBT therapists' judgements of chronic pain
R&D reference: GLOW1601
REC reference:

I am pleased to confirm that the above study has now received a full R&D approval, and you may continue your research in **West London Mental Health Trust**. May I take this opportunity to remind you that during the course of your research you will be expected to ensure the following:

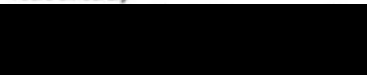
- **Patient contact:** only trained or supervised researchers who hold the appropriate Trust/NHS contract (honorary or full) with each Trust are allowed contact with that Trust's patients. If any researcher on the study does not hold a contract please contact the R&D office as soon as possible.
- **Informed consent:** original signed consent forms must be kept on file. A copy of the consent form must also be placed in the patient's notes. Research projects are subject to random audit by a member of the R&D office who will ask to see all original signed consent forms.
- **Data protection:** measures must be taken to ensure that patient data is kept confidential in accordance with the Data Protection Act 1998
- **Health & safety:** all local health & safety regulations where the research is being conducted must be adhered to.
- **Serious Adverse events:** adverse events or suspected misconduct should be reported to the R&D office and the Research Ethics Committee.
- **Project update:** you will be sent a project update form at regular intervals. Please complete the form and return it to the R&D office.
- **Publications:** it is essential that you inform the R&D office about any publications which result from your research.
- **Ethics:** R&D approval is based on the conditions set out in the favourable opinion letter from the Research Ethics Committee. If during the lifetime of your research project, you wish to make a revision or amendment to your original submission, please contact both the Research Ethics Committee and R&D Office as soon as possible.
- **Monthly / Annually Progress report:** you are required to provide us and the Research Ethics Committee with a progress report and end of project report as part of the research governance guidance.
- **Recruitment data:** if your study is a portfolio study, you are required to upload the recruitment data on a monthly basis in the website: <http://www.crn.nihr.ac.uk/can-help/funders-academics/nihr-crn-portfolio/recruitment-data/>
- **Amendments:** if your study requires an amendment, you will need to contact the Research Ethics Committee. Once they have responded, and confirmed what kind of amendment it will be defined as,

please contact the R&D office and we will arrange R&D approval for the amendment. If your study is Portfolio Adopted, amendments must be submitted for R&D review via the NIHR CRN (CSP), please refer to the Amendments Guidance for Researchers: <http://www.crn.nihr.ac.uk/can-help/funders-academics/gaining-nhs-permissions/amendments/>

- **Audits:** each year, WLMHT select 10% of the studies from each service we have approved to be audited. You will be contacted by the R&D office if your study is selected for audit. A member of the governance team will request you complete an audit monitoring form before arranging a meeting to discuss your study.

We would like to take this opportunity to wish you every success with your project.

Yours sincerely


Maria Tsappis
Research Governance Officer

Appendix 10: Recruitment email

Calling all CBT Therapists!

With your ever-busy caseloads, have you ever wondered how you could possibly find the time to contribute to research and development for your field?


Well here is your answer!


We are looking for CBT Therapists to complete our online questionnaire looking at the factors that affect decisions in treating patients with chronic pain and depression.

Click this link for more information and to access the study:
https://uclpsych.eu.qualtrics.com/SE/?SID=SV_4PxStNGEXcH69iB

Only 15 minutes of your time could make all the difference!

If you have any questions or difficulties accessing the survey, please contact the research lead, Brittni Jones, at [REDACTED]





NHS Foundation Trust

Factors affecting decisions of CBT therapists in the treatment of chronic pain

VOLUNTEER INFORMATION SHEET
Version 1, 16/02/2015

You are invited to participate in a research study. This study aims to increase our understanding of factors affecting the decisions of Cognitive Behavioural Therapy (CBT) therapists in relation to chronic pain.

This study is being conducted by researchers from the Research Department of Clinical, Educational and Health Psychology at University College London and has received ethical approval through UCL. Before we describe the study and its purpose to you we would like to make it clear that it is up to you to decide whether or not to take part. If you choose not to participate, you won't incur any penalties or lose any benefits to which you might have been entitled. Even after agreeing to take part, you can still withdraw at any time and without giving a reason.

Who can participate in this study?

We are inviting qualified CBT therapists working in NHS mental health services to take

part in the study. All volunteers must have good spoken English and good or corrected vision.

What is involved?

Before taking part in the study, you will be asked to give your consent through a computerised consent form. You will then be directed to an online questionnaire that will take approximately 20 minutes to complete. In this questionnaire, you will be shown 3 vignettes paired with images of computer-generated faces that feature patients with chronic pain. After each vignette and its accompanying image, you will be asked questions relating to the patients' experiences of chronic pain and possible treatment decisions.

You will also answer questions about your ethnic and educational background and the training you have received. However, you will not be asked to provide information that could identify you in any way.

What are the risks of taking part in this study?

No risks are envisaged from taking part in this study. The images and vignettes are not anticipated to be distressing.

What are the benefits to me?

You will leave with the knowledge that you have contributed to our understanding of treatment decisions in chronic pain and have helped to further progress psychological research.

How will my data be kept?

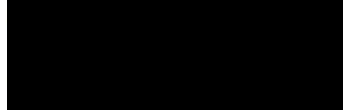
No personal information will be collected about you. Your responses to the online survey will be stored electronically using a numbered code. Only researchers directly involved in the research have access to the data. All data will be collected and stored in accordance with the Data Protection Act (1998).

Who can I contact for further information?

If you have any further questions please contact:

Brittini Jones

Dr. Amanda C de C Williams



You do not have to take part in this study if you do not want to. If you decide to take part, you may withdraw at any time without having to give a reason.

All research projects are reviewed by an ethics committee. This study has received ethical approval from UCL.

Volunteer consent form
Confidential
Version 1, 16/02/2015

Investigators: Brittini Jones, Dr. Amanda C de C Williams

Participant Statement

Please indicate whether you agree with the following statements:

I am a qualified CBT therapist working in the NHS.

Yes

No

I have read the information sheet

Yes

No

I have been advised of whom to contact regarding the research and my rights as a participant, or in the event of a research-related injury.

Yes

No

I have had the opportunity to ask questions and discuss the study via email, and have received satisfactory answers to all my questions.

Yes

No

I understand that I am free to withdraw from the study without penalty if I so wish.

Yes

No

I understand that no identifying information will be gathered about me.

Yes

No

I consent to the processing of my responses for the purposes of this study only. I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.

Yes

No

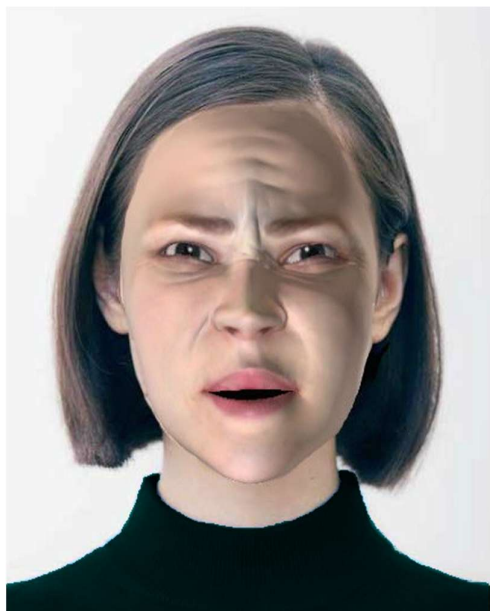
I agree to participate in this study.

Yes

No

Appendix 12: Computer-generated patient faces and pain expressions

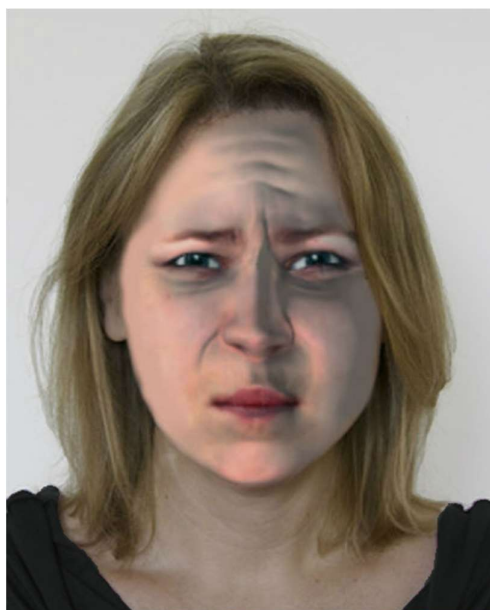
White Face 1 – Expression A



Asian Face 1 – Expression A



White Face 2 – Expression B



Asian Face 2 – Expression B



White Face 3 – Expression C



Asian Face 3 – Expression C



Appendix 13: Written vignettes

Vignette 1: Medically explained pain only

■■■■ is a 32-year-old woman who was referred to your service by her GP.

The referral states that ■■■■ visited her GP about 8 weeks ago complaining of back pain, and scans showed that she was suffering from a slipped disk in her spine. The GP notes that ■■■■ seems to be depressed (low in mood, tearful, not engaging in enjoyable activities), and requests treatment for this.

In her assessment, ■■■■ reports that her low mood and back pain started a little over a year ago. She tells you that her back is intensely painful, and she feels unable to do the things she enjoys like walking her dog. She also finds it a struggle to do things she needs to do, such as carrying her shopping or washing the dishes. As a result of this, ■■■■ reports that she has been feeling low in mood.

Vignette 2: Medically unexplained pain only

■■■■ is a 34-year-old woman who was referred to your service by her GP.

The referral states that Sarah presented 6 weeks ago complaining of chronic back pain, but scans of her spine showed no abnormalities. The GP reports that ■■■■ seems to be experiencing symptoms of depression (low mood, difficulty sleeping, tearfulness), and he is referring her to your service for assessment and treatment of these difficulties.

In the assessment, ■■■■ tells you that her low mood and back pain both started about 1 year ago. She describes her back pain as intense and debilitating, and reports that it has made it difficult for her to do things she enjoys, like playing with her son, ■■■■. She also says that she has found it increasingly difficult to engage in exercise and other physical activities. These limitations have left her feeling frustrated and low in mood.

Vignette 3(a): Medically explained pain with comorbid CFS

■■■■ is a 33-year-old woman who was referred to your service by her GP.

The referral states that ■■■■ visited her GP approximately 9 weeks ago, complaining of fatigue and chronic pain back pain. He explains that she was found to be suffering from a compressed nerve in her spine, and was also diagnosed with Chronic Fatigue Syndrome (CFS). The GP also notes that ■■■■ seems to be depressed (low mood, tearfulness), and requests support for this.

In her assessment, ■■■■ says that her pain, fatigue and low mood started about 1.5 years ago. She tells you that her pain and fatigue have been severe and debilitating, and that she has struggled to do the things she enjoys, such as going out to see friends and family. ■■■■ reports that she finds it difficult to engage in physical activity, and has spent increasing amounts of time at home as a result.

Vignette 3(b): Medically unexplained pain with comorbid CFS

■■■■ is a 33-year-old woman who was referred to your service by her GP.

The referral states that ■■■■ visited her GP approximately 9 weeks ago, complaining of fatigue and chronic pain back pain. He explains that no abnormalities were found in her scans, but she was diagnosed with Chronic Fatigue Syndrome (CFS). The GP also notes that ■■■■ seems to be depressed (low mood, tearfulness), and requests support for this.

In her assessment, ■■■■ says that her pain, fatigue and low mood started about 1.5 years ago. She tells you that her pain and fatigue have been severe and debilitating, and that she has struggled to do the things she enjoys, such as going out to see friends and family. ■■■■ reports that she finds it difficult to engage in physical activity, and has spent increasing amounts of time at home as a result.

Appendix 14: Internet-based questions

Part 1: Experiment Proper

1.1 Directions

For this study, you will be presented with three patient faces and vignettes and will be asked questions on each. Please read each vignette carefully and answer every question.

1.2 Online questions (note: name of patient changed according to the vignette used)

Please answer the following questions on your opinions of Sarah.

How severe do you think [redacted] pain is?

0	No pain	1	2	3	4	5	6	7	8	9	10	Worst possible pain
<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

How much do you think [redacted] is exaggerating her pain?

0	No exaggeration	1	2	3	4	5	6	7	8	9	10	Strong exaggeration
<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

How much do you think [redacted] is minimising her pain?

0	No minimisation	1	2	3	4	5	6	7	8	9	10	Strong minimisation
<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

How likely is it that [redacted] pain is caused by a mental health problem?

0	Very unlikely	1	2	3	4	5	6	7	8	9	10	Very likely
<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

	0											10
	Very											Very
	unlikely	1	2	3	4	5	6	7	8	9		likely
How likely is it that [redacted] pain is caused by a physical health problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Treatment Options

Please rank the following treatment options for Sarah in order of most preferred (top) to least preferred (bottom). Please also indicate if you are unfamiliar with a treatment option.

Items	Most preferred (top) to least preferred (bottom)
CBT for depression	
Specific treatment protocol for chronic pain	
Referral to a pain management service	
Referral to a specialist Health Psychology service	
Contact GP for further information on pain	
	Unfamiliar with treatment option

Part 2: Participant information questions

(Note: all options were selectable in the online format)

Please answer the following questions on your ethnic and educational backgrounds.

The following question asks about your ethnic background and gives broad categories for you to respond with. These broad groups are used to ensure that you are not identified by this information.

What is your ethnicity?

White/White British

Black/Black British

Asian/Asian British

Mixed/Multiple Ethnic Groups

Other

Do you consider your educational background before IAPT to be predominantly medical (i.e. nursing) or non-medical?

Medical

Non-medical

Have you received any training in psychological therapy for people with chronic pain, medically unexplained symptoms and/or long-term health conditions?

No training

Training, duration 1 day or less

Training, duration of more than 1 day

Was this training part of your core IAPT training or was it additional (i.e. Continuing Professional Development [CPD])?

Part of core IAPT training

Additional training (i.e. CPD)
